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A Thesis

Presented in Partial Fulfillment of the Requirements for
the degree Master of Science in the
Graduate School of The Ohio State University

by

Douglas Alan Apsey, O.D.

* * * * * * *

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1991

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CHAPTER I

INTRODUCTION

Probably the most important of the senses used by a pilot while operating an aircraft is his sight. This was especially true in the early days of aerial combat when the pilot who spotted his opponent first usually had the advantage. As the popular World War II saying states, "A pilot's eyes are his best weapon." With the radar and weapons systems that are carried aboard modern fighter aircraft, one might assume that sight is less important to today's pilot than in the past. However, pilots are still required to have good distance visual acuity to ensure that they are able to see and avoid other aircraft, while good near acuity is needed to monitor the instrument panel and clearly read aerial charts, approach plates, and check lists.(1) As aircraft become faster and more sophisticated, the visual demands placed on the pilot are even greater. This is especially true for modern day fighter aircraft which routinely fly at supersonic speeds while requiring the pilot to monitor sophisticated flight instruments, assess radar information, and operate communication, navigation, and weapons systems. This complex visual environment requires that the pilot have unimpaired vision at all working distances. Any factor that affects vision, be it environmental, medical, or optical, is of importance to the aviator and must be eliminated or corrected in such a way as to provide optimal visual performance.

Vision defects, especially refractive errors, eliminate a large number of otherwise acceptable individuals from commercial and military pilot training programs. United States Air Force vision standards screen out all but those with minimal refractive errors.(2) Despite these standards, the USAF estimates that 27% of its pilots are now wearing corrective lenses while performing their flight duties.(3) Without the use of corrective lenses by these individuals, it is likely that their flying careers would have to end and the government would have to spend a significant amount of time and money to train a replacement pilot.(4) Until recently, spectacles were the only approved method for correcting the refractive errors of aircrew members in the USAF. Contact lens wear by aircrew members was forbidden, not only while performing their flight duties but even when off duty. Any surgical correction of refractive error has been and still is considered an unacceptable means of correcting refractive error and is not an allowable option for Air Force aviators.

As contact lens materials have improved and as aircraft and their systems have become more complex, contact lens wear by military aviators has become a more attractive option for the correction of refractive error. Contact lenses are generally more compatible than spectacles with life-support systems, personal protective devices, and helmet-mounted targeting sights that are used in today's military aircraft. Despite these advantages, there are valid concerns about the use of contact lenses in the aircraft environment. These concerns include lens performance under severe gravitational (G) forces, the low atmospheric pressures and reduced oxygen levels, and the low humidity levels that aviators are exposed to while flying in today's high performance fighter aircraft.(5) After extensive evaluation and much debate, the Air Force made the decision to allow the use of soft (hydrophilic) contact lenses as an alternative to spectacles for all aircrew members in July of 1989.

While soft spherical and toric contact lenses are now being worn on a routine basis by Air Force pilots and other aircrew members, the use of rigid lenses has not been approved and is still under investigation. Although rigid lenses are usually considered to be optically superior to soft lenses(6), several factors have kept them from being approved for use in the aircraft environment. These include concerns about displacement or dislodgment during periods of acceleration which generate high gravitational (G) forces(2,7), the possibility of bubble formation behind the contact lens causing decreased visual acuity, discomfort, and epithelial changes(8,9,10), foreign body entrapment under the lens causing severe discomfort or even temporary incapacitation of the pilot (11,12,13), and lens intolerance by a significant number of individuals.(12)

Despite these concerns, rigid gas permeable lenses may have some significant advantages as compared to soft contact lenses in the aerospace environment. Certainly the higher oxygen permeability coefficients (Dk) of rigid gas permeable lenses as compared with hydrophilic lenses is a physiological advantage. Rigid gas permeable lenses do not dehydrate as do soft lenses in low humidity conditions, therefore lens fit and visual acuity should remain more stable .(14,15,16) Rigid lenses do a much better job of correcting astigmatism in most cases and therefore acuity is often superior with rigid lenses versus soft lenses.(6) This is an important factor considering that of the 27% of pilots who require corrective lenses in the Air Force, 33% have 0.75D or greater of astigmatism which is considered visually significant.(3)

In April, 1989, the Softperm contact lens was introduced by Sola/Barnes-Hind. This unique lens combines the high quality optics of a rigid lens, the comfort of a soft lens, and the benefits of oxygen permeability by polymerizing a rigid gas permeable center to a soft hydrophilic skirt.(17) It would appear that this lens design might be ideal for the aerospace environment since it should have the benefits of a soft contact lens including less tendency to decenter under G forces, less probability of foreign body entrapment, and good comfort, while providing the superior optics of a rigid lens. One concern about the use of the Softperm lens in the aerospace environment is its rather low oxygen permeability coefficient (Dk) which is a critical consideration in low atmospheric pressures and reduced oxygen levels experienced by the flightcrew members of high-performance jet aircraft.

Study Objectives

The purpose of this study was to evaluate the Softperm contact lens in both a normal and a simulated aircraft environment to determine its potential use by USAF aviators while performing their flight duties.

Specific objectives were:

1. To determine if significant hypoxic stress occurred to the cornea while wearing the lens in an environment having an oxygen level that simulated 10,000 feet mean sea level (MSL) and a relative humidity of approximately 10%. This was accomplished by measuring corneal thickness with a pachometer at baseline and after 120 minutes of lens wear and comparing these values to see if changes had occurred. Also, other signs of hypoxic stress such as corneal staining, striae, and bulbar conjunctival injection were evaluated and compared. These procedures were first done in a normal environmnent and then repeated in the simulated aircraft environment for comparison.
2. The second objective was to determine whether there was significant change in LogMAR visual acuity with the Softperm contact lens after two hours of exposure to the simulated aircraft environment as compared to two hours of lens wear in a normal environment.
3. The third objective of this study was to determine what effect the low humidity of the simulated aircraft environment had on lens fit characteristics after two hours of lens wear. Also, changes in the amount of tear debris and lens debris after two hours of lens wear were evaluated. A comparison of the changes that occurred was

made between the normal and the simulated aircraft environment.

4. The fourth objective of this study was to evaluate how well the Softperm lens corrected the refractive errors of the subjects. This was accomplished by measuring visual acuities and doing over-refractions to determine the amount of residual astigmatism. The amount of lens flexure was also determined.

5. The final part of this study included a questionnaire to assess subjective comfort and vision during exposure to the simulated aircraft environment.

CHAPTER II

HISTORICAL BACKGROUND AND LITERATURE REVIEW

History of Contact Lenses in Aviation

The idea of pilots wearing contact lenses in place of ordinary spectacles is by no means a new one. In a 1944 study, Jaeckle evaluated scleral lenses in an attempt to answer the question, "Can contact lenses be used practicably in planes at the altitudes commonly attained in modern warfare?"(8) Jaeckle concluded that these lenses were not satisfactory for use at altitudes greater than 18,000 feet due to bubble formation under the lens that may diminish vision, but this finding did not contraindicate their use at lower altitudes. The advent of the Tuohy corneal contact lens in 1948 created an increased interest in the feasibility of the use of contact lenses by aviators.(2) In a 1952 report, Duquet discussed the potential advantages of corneal contact lenses in place of spectacles for the ametropic flier but concluded that the average length of time of eye tolerance for contact lenses was too short and therefore did not find it advisable to promote their widespread use among flying personnel.(10)

Tredici reported that the United States Air Force first showed serious interest in contact lenses in 1950 when 21 subjects were fitted with corneal lenses. The lenses were poorly tolerated by the subjects and all discontinued wearing the lenses after a short period of time. Between 1955 and 1958, the Air Force evaluated vented plastic scleral lenses on 64 pilots and navigators. It was concluded that the fitting process for these lenses was too involved and time-consuming, and that this type of lens was not satisfactory.(2) In 1959, the Air Force fitted 82 flying personnel with corneal contact lenses. By 1960, only half of these subjects were still wearing their lenses and by 1965, only three of the original 82 were still wearing their contact lenses.(18)

In 1962, Diamond discussed the advantages and disadvantages of contact lens wear in aviation and concluded that contact lenses for aircrew personnel have questionable safety due to their potential hazards. He felt that "the majority of pilots who wear glasses would not derive sufficient practical advantage from corneal lenses to warrant the unnecessary risk of complications at the present state of their development".(19)

Despite the early failures and the apparent negative attitude toward the use of contact lenses in aviation, there remained a continued interest in the possibility of contact lens wear by both civilian and military aviators. In 1965, Wick reported that although there were a number of theoretical hazards to wearing contact lenses while piloting an aircraft, there appeared to be no contraindications. He went on to report that the majority of ophthalmologists who were Aviation Medical Examiners approved of their use in civil aviation and concluded that the Federal Aviation Administration's policy on the use of contact lenses, which required a medical waiver to wear them while flying, was probably too restrictive and should be modified.(13) In December of 1976, the FAA ruled that contact lenses could be worn without a waiver to satisfy distance vision requirements. This ruling applied to both private and commercial pilots.(12)

The introduction of the soft, hydrophilic, contact lens in the early 1970's created an even greater interest in contact lens wear by pilots and aircrew members. In a 1975 study, Polishuk and Raz fitted 10 Israeli pilots with the Bausch & Lomb Soflens and monitored them over a six month period while they performed their routine flight duties. This study found generally favorable results with respect to comfort, vision, and glare while wearing the contact lenses.(11) Several subsequent studies were undertaken to evaluate soft lens performance in actual flight conditions and in simulated high altitude conditions through the use of an altitude chamber. These studies looked at the effect of low atmospheric pressure on lens fit and visual acuity(20,21,22,23,24,25) the effect of gravitational (G) forces on soft lens performance(21,23,25) and the effect of low humidity on lens performance.(23,25,26) These studies found no significant contraindications to wearing soft contact lenses in the aircraft environment and lead the way for extensive soft contact lens testing by the USAF to evaluate their potential use by military aircrew members.

The USAF began evaluating soft contact lenses for possible use by its aviators in the early to mid 1980's. One of the first studies undertaken by the Air Force was to evaluate the effects of hypoxia, induced by low atmospheric pressure, on soft contact lens wear.(27,28) Using a hypobaric chamber to lower the atmospheric pressure to simulate an altitude of 10,000 feet, subjects wearing either low water content soft lenses (45%) or high water content soft lenses (71%) were taken on four hour chamber "flights". During the flight, visual acuities were taken and slit lamp observations were made. Visual acuity was found to remain 20/20 or better during all flights although some fluctuation occurred. Both conjunctival injection and tear debris increased over the four hour period and one subject developed striae in both eyes. An increase in corneal fluorescein staining was also reported after the chamber flight. No changes in contact lens fit were noted. It was concluded in this study that despite signs of heightened physiological response by the cornea to the low atmospheric pressure, contact lenses could be safely worn in an environment similar to this.

Another Air Force study during this same time period evaluated the effects that G forces had on spherical and toric soft contact lens centration. Previous investigators had found that soft lenses remained centered even at +6 Gz (vertical or z-axis G forces) or more.(11,21,23,25) This study, using human subjects in a centrifuge, found similar results up to a maximum test level of +8 Gz.(29)

In a 1986 study by Flynn et al., the effects of altitude on soft contact lens wearers was evaluated in a hypobaric chamber at Brooks AFB, Texas. Although there was a heightened response to several of the indicators of corneal physiological stress, such as corneal epithelial staining and conjunctival injection, there were no significant visual acuity changes or other symptoms that would preclude the use of soft contact lenses during exposure to low atmospheric pressure.(30) Flynn et al. also evaluated soft contact lenses for subcontact lens bubble formation in the hyperbaric chamber.(9) This was a problem reported in earlier high altitude studies with PMMA scleral(8) and corneal contact lenses.(30,31,32) The concern over the bubbles forming beneath the lenses was that it may lead to physiologic and visual acuity degradation although none of these studies has demonstrated this.

In 1988, Dennis et al. evaluated soft contact lenses under actual inflight conditions aboard an Air Force C-5 transport aircraft. This study found that there was not sufficient degradation in visual performance or lens comfort to obviate soft lens wear in military transport aircraft.(33) A USAF field study to evaluate the possible use of soft contact lenses by Tactical Air Command (TAC) aviators was implemented in 1988. Eighty-five aircrew members at five TAC bases were fitted with soft lenses and monitored for one year.(34)

Although the conclusion and final report of the study have not been published, based on the preliminary results of that study and on the positive results of the previous studies discussed, the United States Air Force gave approval for the wear of soft spherical and toric contact lenses by its tactical fighter, attack and reconnaissance aircraft pilots and aircrew members in June of 1989.(35) Approval for all other Air Force pilots and aircrew members, including bomber and transport aircraft, soon followed. The overriding reason given by the Air Force for approving the use of contact lenses in the Tactical Air Forces (TAC) was to increase the combat capability of its fighter pilots.(36)

THE NEED FOR VISUAL CORRECTION IN THE MILITARY AVIATION POPULATION

Certainly there would be no issue to discuss concerning the need for or the safety of contact lens wear in military aircraft if there were not a significant number of military aviators who required visual correction. Despite the military's stringent vision standards for acceptance into flight training programs,(37) a significant number of its' pilots and other aircrew members end up requiring corrective lenses before they even begin their flying careers, or soon after they begin. The Air Force has found this to be especially true for USAF Academy graduates.(38) In a 1988 survey, Miller et al. found that only 8.6% of USAF Academy cadets wore spectacles at the time of entry to the Academy while 33.3% were wearing spectacle corrections by the time they entered pilot training. When all pilots were considered together, regardless of mode of entry (AFROTC, OTS, &

USAFA), it was found that only 5.7% required spectacle correction when they entered active duty, 14.9% of these individuals required spectacle correct on by the time they entered pilot training, and 27.4% were wearing spectacle correction at the time the survey was done.(3) The most probable explanation for this increase in refractive error is that these individuals are in their late teens to early twenties, an age where myopic changes often occur.(38,39)

The most significant findings of the study by Miller et al. were that 27.4% of USAF pilots, 51.5% of USAF navigators and weapons controllers, and 40.2% of all other aircrew members were required to wear spectacles when performing their flight duties. The majority of the pilots, navigators, and other aircrew members were found to be myopic (80.5%, 91.7%,, and 82.5% respectively).(3) These values were slightly higher then those found in an earlier USAF study that reported the incidence of spectacle wear by pilots to be 19.6% and that of navigators to be 50.0%.(4) The Army estimates that 18% of its aviators must wear corrective lenses(40) while the Navy estimates that 19% of its' pilots and 90% of its naval flight officers (navigators, bombardiers, etc.) must wear corrective lenses.(12)

A concern when fitting contact lenses is the amount of astigmatism present. It has generally been accepted that 0.75D or more is visually significant and should be considered when fitting soft spherical contact lenses. (41) Miller et al. found that of the 27.4% of USAF pilots who required a spectacle correction, 33.1% had 0.75D or more of astigmatism while 40.8% of the navigator/weapons controllers had this amount or more. This data demonstrates the need for fitting toric soft contact lenses as well as spherical lenses when contact lenses are fitted to meet the visual needs of USAF aviators.

THE ADVANTAGES/DISADVANTAGES OF CONTACT LENS WEAR IN MILITARY AIRCRAFT

Prior to the approval of soft contact lenses for Air Force aircrew members in 1989, contact lenses were allowed only when medically or optically indicated. Some examples included conditions such as keratoconus, aphakia, anisometropia, and corneal scarring, or in other special situations such as equipment incompatibility. Tredici and Flynn reported on 55 USAF aircrew members fitted with either soft or rigid contact lenses in an attempt to allow them to return to active flying duties. Of the 55 subjects, 51 were able to return to their flying duties while four remained grounded due to other medical conditions not related to their visual problems.(2) This study pointed out the value that contact lenses may have as an alternative to spectacle correction in special situations or with certain ocular conditions.

Aircraft and their systems have become much more sophisticated over the years, and therefore the visual demands placed on the pilot have become significantly greater. It is critical that the pilot have unimpaired vision at all working distances in this complex visual environment. Any factor that affects vision, be it environmental, medical, or optical, is of importance to the aviator and must be eliminated or corrected in such a way as to provide optimal visual performance.(2)

Spectacles were the only approved method for correcting the refractive errors of USAF aviators until the approval of contact lenses. A driving force behind this policy change by the Air Force has been the limitations of spectacles in the military aircraft environment. Spectacles have become a significant compatibility problem with many of the advanced optical systems, life support systems, night vision goggles, chemical protective gear, and other personal protective gear.(12) Their weight under Gz forces or heavy vibration can cause them to displace and they can become uncomfortable when worn for long periods under helmets and headsets. Spectacles also limit the field of corrected vision which can create a disadvantage in the air-to-air combat scenario. Contact lenses provide more natural vision since they are located on the eye, not in front of it, and therefore eliminate many of the problems that are found with spectacle corrections. Contact lenses are certainly not without there problems in the aerospace environment however. Tables 1 and 2 list some of the advantages and disadvantages of the use of contact lenses in the aerospace environment while Table 3 lists some of the advantages and disadvantages of spectacles in the aerospace environment.(2,12,13,19,25,27,40,42) In the complex visual environment of today's military aircraft, it appears that USAF has concluded that the benefits of contact lens wear outweighs the risks involved.

THE MILITARY AIRCRAFT CABIN ENVIRONMENT

The Visual Environment

The physical demands placed on the military pilots and crewmembers of today's sophisticated high-performance aircraft can only be exceeded by the visual demands these complex aircraft place on them. Not only are pilots expected to see and avoid (or intercept) other aircraft, both of which may be flying at supersonic speeds, but they must also monitor flight instruments, assess radar information, and operate communication, navigation, and weapons systems. Within the cockpit, instrument and switch panel distances often vary from as little as 16 inches to over 40 inches and are located not only straight ahead but overhead, to the right of and to the left of the pilot. Print size on most instrument and switch panels ranges from 20/30 to 20/70 Snellen equivalent (at 14 inches).(43) The fine print found on aerial charts, landing approach plates, and operational checklists, combined with dim cockpit lighting, place even more demand on the visual system.(1) This highly demanding and complex visual environment requires that the pilot have unimpaired vision at all working distances.

The Physical Cabin Environment

When defining the aviation environment, it becomes apparent that there is not just one environment, but rather several distinct environments that differ depending on the aircraft type and mission it was designed for. United States Air Force aircraft can be placed into basically three categories on the basis of their cabin environment.

The first category includes fighter aircraft, attack aircraft, and reconnaissance aircraft and is designated FAR. The typical mission for FAR aircraft usually involve high speed, high altitude, flights lasting one to four hours. The crew can expect to be subjected to high Gz forces, low humidity, low oxygen levels, plus some gases, fumes, and dust/dirt particles. Often, air flow from air conditioning or outside air vents is high but can be regulated. The newer aircraft in this category have cabin pressurization to offset the high altitudes. This system is activated at approximately 8,000 feet altitude and is able to hold the cabin pressure constant until the aircraft reaches about 23,000 feet at which point the system cannot compensate fully but maintains a pressure differential of 5 psi. As an example, at 30,000 feet, the cockpit cabin pressure would be equivalent to 12,000 feet while at 40,000 feet, the cabin pressure would be equivalent to 17,000 feet.(12,30) Figure 1 shows an example of a cockpit pressurization chart for a modern military fighter aircraft. Some of the older FAR aircraft that are still in service may expose the crewman's eyes to atmospheric pressures equivalent to altitudes of 25,000 feet.(30)

The second category includes tanker (refueling) aircraft, transport aircraft, and bomber aircraft and is designated TTB aircraft. The typical mission for TTB aircraft would involve lower speeds and lower equivalent altitudes than FAR aircraft but are often considerably longer in duration. The crew would be subjected to low humidity, low oxygen levels, high ozone concentrations, (44,45) possible fumes and smoke (including cigarette smoke), and dust/dirt particles.(12) Cabin air flow is often high but can be regulated or diverted. Cabin pressure is better controlled in this type of aircraft so that a near sea-level atmosphere can be maintained up to an altitude of 23,000 feet. At 30,000 feet, the cabin pressure is equivalent to 3,500 feet and at 40,000 feet, it is equivalent to 8,000 feet.(12,20) TTB aircraft do not subject their aircrew to the severe Gz forces often experienced in FAR aircraft.

The third category is the helicopter which has a significantly different environment than the FAR or TTB aircraft. The typical helicopter mission involves low speed, low altitude flights of short duration. Turbulent airflow with high particulate matter is the major concern in this type of aircraft while low oxygen, low humidity levels are of little concern.(12,40) In this study, the helicopter cabin environment will not be addressed.

The primary Air Force concerns with the use of contact lenses in both the FAR and the TTB environments are low atmospheric pressure/low ambient oxygen, and low relative humidity/high air flow and the potential risks these factors pose to the eye.(46) Bubble formation beneath the lens at high altitudes and during rapid decompression causing decreased visual acuity, lens discomfort, and epithelial changes have also been a concern.(9,12,32) Specific to the FAR environment is the concern of lens displacement or loss due to the effects of high Gz forces.(29)

THE EFFECTS OF INCREASED GRAVITATIONAL FORCES ON CONTACT LENSES

A primary concern when considering the wear of contact lenses by aircrew members in high-performance aircraft is the potential for displacement of the contact lens from the center of the cornea or even loss of the lens from the eye due to the rapid onset of gravitational (G) forces.(47) This G force is usually in the +Gz direction during most air combat maneuvers meaning that the force is along the vertical axis or z-axis (head to foot).(48) During high G maneuvers, if a contact lens were to displace, it would be expected to move downward from the central cornea toward the lower limbus or even into the lower cul-de-sac. Miller has identified six basic forces acting on a corneal contact lens applied to the eye. They are atmospheric pressure, hydrostatic pressure, tear viscosity, force of gravity, lid force, and surface tension forces. He credits surface tension as the primary factor which is responsible for the adhesion of the lens to the eye. This surface tension created by the prelens tear film acts to "tack" the lens on place. Increasing lens diameter and fitting the lens steeper will increase this adherence.(49) According to Hayashi and Fatt, the most important forces that control the adherence of a contact lens on the eye are gravity, fluid forces, and the lids. The fluid forces acting on a contact lens are surface tension at the periphery of the lens and a pressure reaction force from the thin lubricating tear film on the posterior side of the lens. These forces act together to hold the contact lens on to the cornea while other forces are constantly acting to move the lens from its quasi-equilibrium position on the cornea. G forces, therefore, must be significant enough to overcome the forces holding the lens on the eye in this quasi-equilibrium position.(50)

Tredici and Welsh demonstrated that small diameter (8.2mm) hard corneal contact lenses (PMMA) decentered downward enough to severely reduce visual acuity when the wearer was subjected to forces of +6 Gz in a centrifuge.(51) Draeger evaluated hard contact lens stability in a centrifuge up to +3 Gz and reported no effect on lens position or visual acuity.(24) Morris, after fitting 82 subjects with PMMA corneal contact lenses including 42 pilots and 24 navigators, reported that "despite G forces, dislodgment of the lenses in flight was extremely rare."(18)

Dennis et al. used a centrifuge to determine how well rigid gas permeable lenses maintained position on the cornea under high G forces. Subjects were fitted with two sets of lenses having diameters of 8.8mm to 9.4mm and 9.6mm to 10.0mm. By using a video camera mounted in the gondola of the centrifuge, it was possible to monitor lens position during each ride. At approximately the +4 Gz level, the upper lid of all subjects lost control of the lens and allowed it to drop 2 to 3mm except during a blink. Even at +8 Gz, the upper lid was able to regain control for a short time. The smaller diameter lenses tended to displace downward 0.5mm more than the larger lenses. No lenses displaced completely from the cornea or dislodged from the eye during the study.

It was concluded that overall lens diameter may be the most important factor for centering RGP lenses during high +Gz forces possibly due to greater surface tension and better control by the upper lid.(47) This conclusion agrees with work by Carney et al. which demonstrates, using calculations, that increasing lens diameter enhances lens stability more than changing any other design feature.(52,53)

Soft contact lenses have fitting characteristics that are quite different from rigid lenses. They are significantly larger in diameter and are therefore in contact with more of the ocular surface. They are also flexible which allows them to drape over the cornea and sclera, thus aligning more closely with the ocular surface. These lenses tend to center well and move very little. The movement of soft lenses is less than rigid lenses due, in part, to a thinner tear film behind the soft lenses. Because of these differences, G forces tend to cause less decentration of soft contact lenses as compared to rigid contact lenses.

This was demonstrated by Flynn et al. using a centrifuge to evaluate soft contact lens centration characteristics and visual performance under high +Gz conditions.(29) Using a video camera to monitor lens decentration during each ride, the maximum decentration observed with spherical soft lenses was less than 2mm while toric soft lenses decentered slightly more to an estimated 2mm maximum at +8 Gz. Visual acuity was slightly reduced with both lens designs at +6 Gz and +8 Gz but this reduction also occurred when spectacles were worn by the subjects and was thought to be a physiological (retinal ischemia) rather than an optical consequence.

Brennan and Girvin performed a similar investigation on seventeen Royal Air Force aircrewmen and found that the maximum lens displacement at +4 Gz and +6 Gz was 1.5mm and 1.75mm, respectively.(25) Several studies have been done evaluating soft contact lenses in actual inflight conditions. Polischuk and Raz stated that there were no adverse reactions reported by any of the ten pilots they had fitted with soft contact lenses while performing military flight maneuvers that created up to +6 Gz forces.(11) Nilsson and Rengstorff reported on a Swedish Air Force fighter aircraft pilot who wore soft contact lenses for more than two years while performing his flight duties. He was also tested in a centrifuge and had no problems with the lenses when exposed to a maximum force of +6 Gz.(21)

THE EFFECTS OF LOW HUMIDITY ON CONTACT LENSES

Discomfort while wearing contact lenses on long commercial airline flights has been reported in the literature on several occasions.(26,54,55,56) Jagerman, an ophthalmologist practicing near a major international airport, reported treating a large number of patients having central corneal overwear abrasions after completing long, non-stop, high altitude airplane trips. He felt that insufficient atmospheric oxygen and/or rapid tear evaporation due to low cabin humidity may be causing a "hypoxic cornea" syndrome.(54)

Eng reports that flight attendants, especially contact lens wearers, have complained about eye discomfort in aircraft.(55,56) In a survey of 774 flight attendants, 97% of the 105 who wore soft contact lenses and 95% of the 219 who wore hard lenses reported experiencing more dry eye symptoms while wearing the lenses in flight as compared to on the ground.

Some of the flight attendants were unable to wear their lenses in flight, but were comfortable with them on the ground. Some of the factors that exist in the aircraft cabin environment that may contribute to this eye discomfort include low relative humidity, low oxygen partial pressure, smoke or other fumes,(12,55,56) and high ozone levels in the aircraft.(44,45) It is still not entirely clear as to whether this discomfort is caused by a single factor or a combination of these factors despite attempts to isolate the cause. Eng feels that the low relative humidity of the cabin is the major contributing factor in soft lens discomfort,(20,26) while Hapnes suggests that corneal epithelial hypoxia due to the low oxygen pressure is the main cause of this lens intolerance.(22)

Flynn evaluated soft contact lens wearers at ground level and 10,000 feet using two relative humidity conditions (5% & 10%) at each altitude and reported that subjects noted an increase in lens awareness only with the 5% relative humidity condition at ground level. Lens awareness during both humidity conditions was reported at 10,000 feet.(27,30) This suggests that both low humidity and low atmospheric pressure could be the cause of this discomfort which is in agreement with Castren who feels that the cumulative effect of the combination of low atmospheric pressure and low humidity could explain the numerous eye symptoms of the "jet-set disease" as he calls it. Castren reports that a relative humidity level of 40% to 60% is considered optimum for eye comfort.(23) At least two studies have reported no eye discomfort or dry eye sensation while wearing soft contact lenses in the aircraft environment.(21,24)

The decrease in relative humidity that occurs within an aircraft cabin at altitude is quite substantial. Relative humidity levels in commercial aircraft have been reported to decline from 47% to 11% within fifteen minutes after takeoff.(26) These data are similar to measurements made by the author on two commercial flights where relative humidity declined from 49% to 19% on the first flight and 47% to 20% on the second.(57) Military aircraft are reported to have a typical relative humidity level of 10 to 15%.

Fighter aircraft which normally carry only one or two crewman may have even lower cockpit humidity levels. Measurements were taken using a small relative humidity pen in two F-16 aircraft while flying over the Nevada desert and both aircraft reached a minimum of 5% during the flight. These flights were below 8,000 feet altitude and the ambient ground level relative humidity was 16% for the first flight and 13% for the second. During an evening flight in an F-15 aircraft at altitudes of 37,000 to 41,000 feet, the relative humidity was as low as 3% . Ambient relative humidity on the ground before take-off was 10%.(57)

Respiration and perspiration from the occupants of commercial aircraft probably accounts for most of the moisture in the cabin air and the higher relative humidity readings as compared to military aircraft.(26)

Studies have shown that hydrophilic lenses dehydrate when worn in low humidity environments.(58,59,60,61,62) Andrasko and Schoessler found that hydrophilic lenses retain only 81% to 94% of their original water content depending on environmental factors such as air temperature, relative humidity and wind velocity.(61) Other factors such as lens thickness and water content, tear characteristics, eyelid position, and blinking may influence the amount and speed of dehydration.(63) Dehydration of the contact lens has been shown to alter it's diameter, base curve, modulus of elasticity, and thickness. These changes may adversely affect the fitting characteristics of the lens, the comfort of the lens, and vision through the lens.(64,65,66,67,68,69,70)

Andrasko evaluated several factors that may influence soft contact lens dehydration, including lens factors, environmental factors, and patient factors.(63) Thin lenses lost a higher percentage of their water content than thicker lenses of the same material and lenses made of higher water content material dehydrate a greater amount, faster, and reach equilibrium sooner than lenses of similar thickness but lower water content. Relative humidity had a definite effect on lens dehydration. When exposed to a high humidity (94%) environment, medium (55%) water content lenses in vivo dehydrated 8.9% while high (71%) water content lenses dehydrated 8.6%. In contrast, in an environment having a relative humidity of 18%, the medium water content lenses dehydrated 14.1% while the high water content lenses dehydrated 18.4%.

Hamano also found that high water content lenses suffer from considerable dehydration during the initial ten minutes of wear.(65) Fatt, using a theoretical study of gel dehydration, has shown that lower water content hydrogel lenses will undergo smaller changes in hydration when exposed to a dry environment.(71) Other studies have also demonstrated that the greatest water loss occurs in lenses having the highest initial water content.(67)

Brennan states that the primary factors contributing to the dehydration of hydrogel lenses during wear are an elevation in temperature on application to the eye (as compared to the "room" temperature), and the evaporation from the anterior surface of the lens into the atmosphere. Conditions such as decreased humidity along with the increase in temperature that occurs when the contact lens is placed on the eye may lower the steady-state water content of the lens during wear.(69,72,73) Fatt has suggested two possible mechanisms for hydrophilic contact lens dehydration. He stated that evaporation of water from the anterior surface of the hydrogel lens is the most likely cause of dehydration. This process can only occur if the tear layer breaks apart during the open-eye period of the blink, therefore exposing the surface of the lens.(74)

Cedarstaff and Tomlinson evaluated the effect that soft contact lens wear had on the tear film and found that soft contacts disrupt the tear film sufficiently to facilitate evaporation from the anterior surface of the lens. This increase in evaporation may be due to the breakup of the lipid layer on the front surface of the tears.(67)

Yet, hydrogel lenses do not totally dehydrate while in the eye. The lens will reach an equilibrium water content at which point the amount of water lost by evaporation during the broken phase of the tear film interval is exactly matched by the gain in water during the closed eye, intact tear film, interval. If the loss of water were greater than the gain, the lens would eventually totally dehydrate. This phenomenon is not seen clinically.(74) Such factors as initial water content, lens thickness, polymer hydration properties, and patient factors may influence the time course of hydrogel lens dehydration. (75) Environmental factors such as relative humidity, air temperature, and air turbulence also effect the degree of in vivo lens dehydration.(69)

According to Fatt, another possible mechanism of lens dehydration is evaporation from the tear film followed by water withdrawal from the lens by an osmotic process (a temporary hyperosmotic tear film during the open eye part of the blink cycle withdraws water from the lens). This would lead to a cycle of iso-osmotic and hyperosmotic tear fluid which may cause a cyclic dehydration and rehydration of the contact lens surface. Either mechanism of lens dehydration would lead to a cyclic dehydration and rehydration of the hydrogel lens at its anterior surface, with dehydration occurring during the open eye period of the blink phase and rehydration occurring when the eye is closed and the tear film is restored. This cyclical process must allow as much water to be reimbibed during the rehydration period as was lost during the drying period. Under any other conditions, equilibrium could not occur and the lens would continue to increase or decrease in water content.(74)

The significance of soft contact lens dehydration as it relates to the aircraft environment are the effects that dehydration have on lens fitting characteristics and lens oxygen permeability (Dk). As previously stated, when a soft contact lens dehydrates, it shrinks and there are parameter changes that occur. Some hydrogels are isotropic, meaning that they shrink the same amount in all directions while others are anisotropic, or shrink different amounts in different directions.(74) This shrinkage results in a slight decrease in lens diameter and thickness, although it is questionable whether this is enough change to significantly influence lens fitting characteristics.(64,76) More important is the steepening of the base curve radius of the lens that occurs during dehydration, which may cause the lens to fit too tightly on the eye.(65)

One might assume that any change that causes the lens to move less may also reduce the lens tear pumping action and increase the possibility of corneal edema. Studies have shown that soft contact lenses pump only small amounts of fresh tears under them with each blink(77,78) and that lens thickness and hydration level, not lens movement, are the principle factors determining the amount of corneal edema with soft contact lenses.(79,80) Therefore, the amount of corneal edema is an individual response dependent upon the oxygen permeability of the lens material, the thickness of the lens, and the oxygen requirements of the individual cornea.(81)

Tightening of the lens on the eye due to lens dehydration may not be a significant concern in the aircraft environment. Several studies have evaluated the effect of low humidity on lens fit characteristics in real or simulated aircraft environments. Dennis, during actual inflight conditions, reported a trend toward a tighter fit but this was not statistically significant.(5) Eng et al., also during actual inflight conditions, reported that changes in lens fit characteristics were related to the change in humidity in the aircraft and were most noticeable as the humidity was sharply reduced.(26) Flynn and Draeger did not detect any changes in lens fit characteristics during hyperbaric chamber "flights".(9,24,27)

Eng, Dennis, and Flynn have all reported a significant increase in conjunctival injection when soft contact lenses are worn in the low oxygen, low humidity environment of an actual or simulated aircraft cabin.(5,9,26,27) Although this may be due to the effects of hypoxia, the tightening of the lens fit, when it occurs, may cause conjunctival compression at the limbus which has been shown to lead to generalized conjunctival injection.(82,83) Limbal injection, poor or variable visual acuity, and ocular discomfort may also occur. Tight fitting lenses may contribute to corneal edema as well.(84)

The major concern over soft contact lens dehydration is the decrease in oxygen permeability that occurs as water is lost from the lens. The permeability of oxygen (Dk) in hydrogel lenses is determined by their water content. As the amount of water absorbed by the lens increases, its permeability to water and water soluble substances such as oxygen also increases.(85,86) Hill and

Andrasko have shown that the oxygen permeability of a hydrophilic contact lens decreases proportionately with water loss.(87) The principle factors that affect oxygen transport across a hydrogel lens are, hydration of the lens, thickness of the lens, consumption rate of oxygen by the cornea, and oxygen concentration over the lens. A hydrophilic contact lens worn in an environment having low humidity will dehydrate resulting in decreased oxygen permeability.(85) This, combined with the low oxygen levels found in an aircraft cabin, could cause the lens to be unable to meet the minimum oxygen requirements of the cornea and hypoxia may result.

Very little has been written in the literature concerning low humidity affects on rigid contact lenses. Eng surveyed flight attendants concerning eye comfort in commercial aircraft and found that 95% of the 219 who wore rigid contact lenses reported an increased frequency of dry eye and 92% reported an increased frequency of eye discomfort while in flight compared to ground level.(55) Nilsson, in a review of contact lens wear in the work environment reported that many contact lens wearers working in dry environments experience considerable eye pain.(88) Tredici reported fitting 37 USAF flying personnel with hard contact lenses to correct medical conditions that affected their vision, the majority of which were able to successfully return to their flight duties.(2)

Bickel studied the effects of lower relative humidity versus higher relative humidity on visual acuity and comfort with rigid gas permeable lenses and found that neither extreme had an affect on visual acuity but low relative humidity either had no affect on comfort or degraded it. High relative humidity was found to have either no affect on lens comfort or improved it. This study also found that, when wearing the flight helmet, the relative humidity immediately in front of the subject's eyes was always higher when the helmet visor was down than it was without the visor in place.(89) These data are consistent with the author's findings during actual flight conditions.(57)

The implication of this information is that the effects of the low cabin humidity can be at least partially offset by using the visor which may help elevate the humidity level immediately in front of the eyes. Tsubota has reported that wearing spectacles such as sunglasses may also increase the humidity immediately in front of the eye. He found a 17% increase in the humidity level in front of the eyes with regular spectacles and a 50% increase when spectacles with side panels were worn. Spectacles may also be helpful in shielding the eyes from air currents from cabin climate control vents.(90) Of course, an alternative to spectacle wear is what the Air Force is attempting to find and wearing spectacles over contact lenses for any reason seems to defeat the purpose of wearing contact lenses in the first place.

CORNEAL HYPOXIA

Concerns about the effects of +Gz forces and low cabin humidity are certainly valid when considering the use of contact lenses in the aviation environment, but the major concern that has been voiced is the potential effect on the eye of low atmospheric pressure and resultant low oxygen pressure that occurs with increased altitude. The cornea, which is avascular, must depend on ambient air as its primary source of oxygen to maintain its normal metabolic activity. Normal metabolic activity is essential for maintaining deturgescence and the optical quality of the cornea.(91) Therefore, a contact lens placed on the eye must have enough oxygen transmissibility to meet the corneas demand for oxygen. At high altitude, the cornea is exposed to ambient air that has a reduced oxygen partial pressure which reduces the amount of oxygen available to the cornea (hypoxia). The lower ambient oxygen level, combined with reduced oxygen flow through the contact lens can lead to a hypoxic condition significant enough to alter the normal state of corneal hydration (edema). This often leads to symptoms of photophobia, lens discomfort or intolerance, and hazy vision or halos.(91,92,93,94) Corneal hypoxia has been suggested as the cause of contact lens discomfort during high altitude air travel.(22,23)

Altitude, Atmospheric Pressure, & Oxygen Partial Pressure

The driving force for the movement of oxygen through a gas permeable (soft or rigid) contact lens is the difference in partial pressures in front and in back of the lens.(85) Likewise, the rate at which oxygen will enter the cornea is dependent on the partial pressure of oxygen.(95) The partial pressure of a particular gas in a mixture of gasses is an expression of its concentration in that mixture. The total pressure of a gas mixture is the sum of the partial pressures that make up the mixture. The atmosphere of the earth is made up of a mixture of several gases that includes nitrogen (78%), oxygen (20.9%), and carbon dioxide and other gasses (1.1%). The percentages of each of these gasses in the atmosphere remains constant up to 70,000 feet. (Fig. 2)(96) At sea level, the atmospheric pressure is 760mm Hg. This pressure decreases rapidly as altitude increases. For example, at an altitude of twenty thousand feet, the atmospheric pressure is 350mm Hg.(20) The relationship between atmospheric pressure and partial pressure of oxygen (pO_2) is given by equation 1:(85)

1. pO_2/Atmospheric pressure = 0.209

Using this formula, the pO_2 of oxygen can easily be calculated for any altitude. At sea level, under standard pressure, temperature and humidity conditions, the partial pressure of oxygen is 159mm Hg. The actual pO_2 value is closer to 155mm Hg when corrected for water vapor (humidity) and non-standard weather conditions.(95,97) Like atmospheric pressure, the partial pressure of oxygen decreases as altitude increases although, as stated above, the percentage of oxygen in the atmosphere remains at 20.9%. Table 4 and Figure 3 show the relationship of altitude, atmospheric pressure, and partial pressure of oxygen.(20)

Often in the contact lens literature, percent oxygen is used in place of partial pressure of oxygen when describing experimental procedures. This has created some controversy(97,98) but is acceptable, in Mandell's opinion, as long as it is understood that the values are equivalent only at sea level and must be adjusted for other altitudes.(95,99) Fatt reminds us that it is not the percentage of oxygen in the mixture that governs the rate at which oxygen enters the cornea or a gas permeable contact lens, but rather the partial pressure of oxygen (also called the oxygen tension).(97) The main point to remember is that regardless of what term is used to describe it, the amount of oxygen available to the cornea is reduced as altitude is increased.

Another concern with contact lens wear at high altitudes is the formation of bubbles in the tear layer between the posterior contact lens surface and the cornea. The theory behind bubble formation under a contact lens is that small bubble nuclei (small gas bubbles) are present in the tear film between the cornea and the contact lens that expand as altitude increases and atmospheric pressure subsequently decreases.(9) Subcontact lens bubble formation was first reported by Jaeckle in 1944, who noted bubbles forming under scleral contact lenses at simulated altitudes of 18,000 feet and higher. Jaeckle concluded that these bubbles may cause diminution of vision although the presence of bubbles under the lens was not always associated with decreased acuity.(8)

Newsom et al. reported bubble formation under PMMA corneal contact lenses at altitudes of 18,000 feet and greater. Two of the sixteen subjects in Newsom's study reported decreased visual acuity associated with large bubbles that had formed under their lenses.(32) Flynn et al. evaluated both soft and rigid gas permeable contact lenses in the hypobaric chamber. Bubbles were noted only at the limbus with the soft contact lenses and had no effect on vision or corneal epithelial integrity. These limbal bubbles were noted at altitudes as low as 6,000 feet and would increase in size and coalesce as altitude increased. They dissipated after several minutes. Rigid gas permeable lenses also developed bubbles under the edges of the lenses at altitudes of 20,000 feet and greater. These disappeared rapidly when the subjects blinked several times. At 25,000 feet altitude, two subjects developed many small bubbles centrally that dissipated upon descent. Visual acuity was unaffected and no epithelial damage was noted. Flynn concluded that soft contact lens wear at high altitudes should not be prohibited by the fear of bubble formation.(9)

Minimum Oxygen Requirements of the Cornea

The rate of oxygen uptake by the cornea (corneal oxygen flux) has been measured using a polarographic oxygen electrode and found to be 4.8 ul/sq. cm of corneal surface/hour.(100) This value represents a weighted average of the oxygen consumption of each layer of the cornea with the epithelial layer accounting for approximately 75% of the oxygen consumption of the entire cornea.(101) Although it makes up 90% of the corneal mass, the stroma utilizes very little oxygen due to the small number of cells present.(102) The endothelium, though only a single layer of cells, has a high oxygen consumption rate due to its high metabolic activity.(103)

Most of the oxygen consumed by the cornea is taken in by the epithelium and the endothelium. The endothelium and posterior stroma receive their oxygen from the aqueous humor, while the epithelium gets much of its oxygen from atmospheric oxygen dissolved in the precorneal tear film or from the limbal capillaries.(102,104,105)

Larke found a wide distribution in human epithelial oxygen uptake rates between subjects, as well as between measurement sessions using the same subject. This variation in oxygen uptake may help explain why patient response to contact lens wear, especially with regard to corneal edema, varies greatly between subjects.(106) Individual variation in human corneal oxygen flux may be due to differences in epithelial thickness, corneal temperature, and basal metabolic rate.(107)

Oxygen deprivation of the cornea has been shown to result in corneal swelling that can effect the optical quality of the cornea. Smelser demonstrated this in 1952 by using air-tight goggles to pass nitrogen over the cornea which resulted in halos similar to those experienced by scleral contact lens wearers.(91) Many attempts have been made to determine the minimum oxygen requirement of the human cornea to avoid edema over the years and the controversy continues as to just what this level is. In 1970, Polse and Mandell exposed human corneas to a reduced partial pressure of atmospheric oxygen in an attempt to determine the minimum oxygen level to avoid corneal hydration and found that a partial pressure of oxygen of 11.4 to 19mm Hg (1.5% to 2.5% oxygen percentage) over a four hour period was the critical level needed to maintain normal corneal thickness.(108) Mandell and Farrell determined that a partial pressure of 23 to 37mm Hg (3.3% to 5.5% oxygen) would totally prevent corneal swelling.(109) Holden et al. determined that a partial pressure of oxygen of 74mm Hg (10.1%) was necessary to avoid corneal edema.(110) Efron and Brennan have gone as far as to say that the critical oxygen requirement (COR) for the cornea is the amount of oxygen available in the air (155mm Hg or 20.9%), and that any level less than that will alter the physiological status of the cornea.(111)

The corneal epithelium is exposed to a partial pressure of oxygen of 155mm Hg near sea level when the eyes are open and approximately 55mm Hg when the eyes are closed.(112) Using a polarographic electrode to measure corneal oxygen uptake during closed eye conditions, Efron and Carney were able to confirm the closed-lid value by measuring an average oxygen tension of 56.7mm Hg.(113) In the closed eye state, approximately two-thirds of the oxygen enters the cornea by diffusion from the capillaries of the palpebral conjunctiva while the remainder enters from the aqueous humor.(114)

Corneal Swelling/Corneal Response to Hypoxia (etiology)

The cornea can be divided into five layers; the epithelium, Bowman's layer, the stroma, Descemet's membrane, and the endothelium.(115) The stroma makes up the majority (90%) of the corneal thickness and consists of collagen fibers of nearly uniform diameter running parallel to one another to form stromal lamellae. There are approximately 200 to 250 of these lamellae making up the stroma. The fibers within each lamellae run at right angles to the adjacent lamellae thus forming a lattice network of unwoven fibers. Each lamellae crosses the entire cornea and is about 2 microns thick. The fibrils and the lamellae are held together by a cement substance composed of mucopolysaccharides and protein.(115,116,117) The five to six cell layers making up the epithelium are responsible for nearly all of the remaining corneal thickness. The average central corneal thickness is generally considered to be about .52 to.53mm and tends to thicken to an average value of .66 to .67mm in the periphery.(103,118,119)

The cornea has been shown to transmit electromagnetic radiation in the range of 295nm to 2500nm with 90% of the light above 400nm being transmitted by young, healthy corneas.(116,117) The transparency of the cornea is determined by its avascularity as well as its morphology and chemical composition. The epithelial cells are not keratinized and their components have a uniform index of refraction. Also, Descemet's membrane and the endothelium do not reflect light at their interface since they each have the same index of refraction.(117) Maurice in 1957 proposed that the corneal (stromal) transparency was due to the unique lattice-like arrangement of the collagen fibers within the stroma.(120) He stated that each line of fibrils corresponds to a diffraction grating with the space between the gratings less than one wavelength of visible light. Benedek in 1971 reported that the cornea does not have a perfect lattice periodicity but is transparent to visible light since the density of scattering particles is the same throughout the stroma. Therefore, the total intensity of the scattered light will be zero. (The medium is perfectly transparent if the density of scattered particles is uniform throughout). (116,121)

Regardless of which theory is correct, the fact remains that the relative dehydration of the stroma is necessary for the cornea to maintain its transparency. The normal, healthy cornea maintains a relatively constant thickness throughout life by achieving a steady water content of 75 to 80% of its weight.(102) To maintain this normal hydration level (deturgescence), the metabolic activity of the corneal epithelium and endothelium must remain undisturbed.(103,117) Through both active and passive processes, the epithelium and endothelium play a major role in the maintenance of corneal transparency. The metabolic activity of the endothelium is the most important in maintaining corneal clarity with passive resistance to water flow by the limiting membranes, intraocular pressure, and other factors playing lesser roles.(103) The epithelium acts mainly as a barrier and has minimal stromal dehydrating ability. The endothelium is 30 times more efficient than the epithelium as a metabolic fluid pump.(122)

Any disturbance to the metabolic activity or physical barrier effect of the endothelium or epithelium can result in increased hydration (edema) of the cornea which results in corneal swelling. Since the cornea is fixed at the limbus, it can only swell in an anterior to posterior direction and therefore increases in corneal thickness can be linearly correlated with increases in hydration. (102,123) Oxygen deprivation (hypoxia) has been shown to interfere with the normal metabolic activity of the cornea and cause corneal edema. As discussed earlier, Smelser showed in 1952 that halos, similar to those reported by scleral contact lens wearers, occurred after nitrogen was passed over the cornea. He concluded that deturgescence and the optical properties of the cornea are maintained by metabolic activity of the cornea, which requires atmospheric oxygen.(91,124)

Mandell et al. found a 7% increase in the corneal hydration in one hour when humidified nitrogen was passed over the cornea.(125) Polse and Mandell found similar results (7.86%) after two and one-half hours of exposure to 100% nitrogen gas.(126) Wilson and Fatt reported 12% corneal swelling after two and one-half hours of exposure to humidified nitrogen. (127) Mandell and Farrell evaluated corneal swelling after exposure to oxygen partial pressures of 0.95%, 2.34%, and 2.77%. The average corneal swelling after four hours was 5.07%, 2.13%, and 1.66%, respectively. This data showed that there was a relationship between corneal swelling and oxygen partial pressure and it was speculated that this relationship was exponential, not linear in nature.(109) Hedsby and Mashima have reported a linear relationship between corneal thickness and corneal hydration levels in rabbit corneas.(123,128)

Numerous studies have shown that the corneal swelling occurs soon after a contact lens is placed on the eye. Smelser and Ozanics demonstrated in 1952 that the water content of the cornea, and consequently the thickness, was increased when a tightly fitted lens was placed on the eyes of guinea pigs.(124) Smelser suggested that contact lenses interfere with the optical properties of the cornea by affecting the water balance of that tissue. This occurred due to the contact lens preventing both maintenance of a hypertonic tear film and access of oxygen to the corneal surface.(91) Hill and Fatt demonstrated that a corneal contact lens can interfere with the flow of oxygen from the air to the cornea under normal wearing conditions.(114) Other studies also showed that corneal thickness changes and central corneal clouding occur within as little as two hours after PMMA contact lenses are placed on the eye.(92,129) El Hage et al. found statistically significant increases in corneal thickness after one hour of hard lens wear and three hours of hydrogel lens wear.(130) Harris et al. measured corneal thickness changes of 12 subjects after wearing both a thin (0.4 to 0.6mm) and a conventional-thickness (0.14 to 0.16mm) Bausch & Lomb F3 lens and found that the thin F3 lenses produced significantly less edema than the conventional-thickness F3 lenses. They concluded that reduced thickness allowed greater oxygen transmission through the thin lenses.(131) This was consistent with the earlier findings of Fatt and St. Helen who demonstrated that the oxygen tension at the anterior corneal surface under a gas permeable contact lens (hydrogel) was a function of the oxygen transmissibility and the thickness of the lens.(132)

Bradley and Schoessler evaluated twenty-four subjects to determine whether or not there were significant changes in corneal thickness over a six month period while wearing thin (0.06 to 0.08mm) and standard thickness (over 0.12mm) daily wear hydrogel lenses. A chronic edema level of 3 to 4% was noted with the standard thickness lenses while the thin lenses caused only a 0.80% increase in corneal thickness.(133) Many studies similar to these have been done to evaluate hydrogel lenses used for extended wear.

Sarver et al. were able to show that more edema occurred during overnight wear with thick (0.18mm) hydrogel lenses than with thin (0.07mm) hydrogel lenses. Both lenses caused more edema (12.7% with the thick lens, 7.9% with the thin lens) than occurred when no lens was worn on the control eye (0.9%).(134) Many other studies similar to these have been done with comparable results. (135,136,137,138) Rigid gas permeable lenses have also been found to cause corneal thickness changes of 10% or more when worn as extended wear.(138,139)

Several of these studies reported that there was a significant intersubject difference in corneal edema response to hypoxia.(106,109,134,135) Sarver et al concluded that these studies suggest that individual amounts of oxygen are required to maintain normal corneal metabolism and that the edematous response to hypoxia will differ among patients. Their own study showed that after three hours of wearing hydrogel lenses designed to stress corneal metabolism by reducing oxygen availability, corneal edema among the thirty subjects varied from 3.7% to 12.2%.(140)

Soft lens induced edema has been found to differ from hard lens edema in that it is normally spread across the entire cornea rather than confined to the central cornea. (141,142,143)

The exact mechanism of corneal edema during lens wear is still being debated. Although it is generally accepted that corneal edema is a result of inadequate oxygen supply to the cornea caused by the lens acting as a barrier to atmospheric oxygen, changes in tear film osmolarity,(80) increased corneal temperature,(144) and reduced corneal pH(145) have also been implicated as possible causes of corneal edema during lens wear. Fatt and Chaston suggested that corneal swelling during contact lens wear is caused by reduction of tear osmolarity, by hypoxia at the anterior corneal surface, or by both.(146)

Brennan and Efron reported that when corneal swelling in response to an anoxic environment created by using goggles to pass nitrogen over the eye is compared to corneal swelling in response to a similarly anoxic environment created with a contact lens in situ, the cornea will swell to a greater degree in the second case. This, they feel, may be due to the added effect of osmotic, temperature, and pH changes that can occur with contact lens wear. The mechanical effect that a contact lens has on the cornea may also play a role in the swelling response of the cornea.(98) Others have also noted this difference in corneal swelling response to these two environments.(147,148,149) O'Neal states that the increased effect of evaporation caused by the gas flowing across the cornea may limit the swelling response that occurs with the gas goggle environment.(149)

Which layers of the cornea swell when it is subjected to an anoxic environment seems to be a disputed issue. It appears to be generally accepted that stromal edema occurs under conditions of inadequate oxygen(150) but there is not complete agreement as to whether the corneal epithelium also swells during periods of anoxia. Uniacke et al. were able to demonstrate that epithelial edema occurred in the rabbit cornea in response to an oxygen free environment.(151) Lowther and Hill, also using rabbit corneas, found similar results to Uniacke et al.(152) Wilson and Fatt found very little epithelial edema occurred when exposing a live rabbit eye to an anoxic environment and concluded that corneal edema due to anoxia is caused almost entirely by the swelling of the stroma. They also noted that although little thickness change occurred, there were epithelial changes that did occur during anoxia that may lead to halos, glare, and visual acuity loss in humans.(153) In a 1980 study, O'Leary et al evaluated the human epithelium after six hours of anoxia and found no significant epithelial swelling.(154) Schoessler and Lowther, under the premise that epithelial edema does exist, feel that epithelial edema indicates excessive or hypotonic tears which may be expected in the first few days of contact lens wear while stromal edema implies that the cornea is not receiving enough oxygen to allow for normal metabolic function. (150) Whether the epithelium swells or not during periods of anoxia is yet to be answered. Regardless of this, the major concern when considering the effects that reduced levels of oxygen have on the corneal epithelium should be how the metabolic activity of the epithelium may be altered by such an environment.

Contact lens wear has been shown to suppress corneal aerobic metabolism and stimulate anaerobic glycolysis by inducing corneal hypoxia.(155) This may lead to lowered metabolic rate, increased epithelial lactate production, and an acidic shift in stromal pH.(145) The reduction in the epithelial metabolic rate may affect mitotic rate of epithelial cells,(156) cellular junctional integrity,(157) and cellular glycogen reserves.(152)

The stroma itself may be effected more indirectly than directly by hypoxia. The reason for this lack of direct effect may be due to the low oxygen requirements of the stroma and its low metabolic rate.(158) The only direct change that may occur to the stroma may be the degeneration of keratocytes and even this may be caused indirectly due to the toxic effects of the high lactate levels in the stroma.(158) Despite this, the corneal stroma shows one of the most prominent effects of hypoxia through its swelling response.(124) Klyce has proposed that stromal edema results from the build-up of lactic acid, which is a by-product of anaerobic metabolism. The lactic acid is slowly diffused through the stroma to the anterior chamber. The concentration of lactic acid in the stroma increases to a point where it provides sufficient osmotic pressure to explain the rise in corneal hydration. (159)

Other Indicators of Corneal Hypoxic Stress

Many individuals suffering from corneal edema will report that they have hazy or foggy vision, ocular discomfort, and conjunctival injection.(160) Eng reported that flight attendants often complained of both discomfort and conjunctival injection while wearing contact lenses in flight.(55) Several studies have reported a significant increase in conjunctival injection when contact lenses were worn by subjects during simulated and actual high altitude flights.(20,27,30,34) Although conjunctival injection has been associated with corneal hypoxia,(82) it may be as much a result of the low humidity levels encountered in aircraft cabins at altitude.(34) Brennan reports that the conjunctiva may be one of the better indicators of problems during contact lens wear but it has received very little attention. Conjunctival injection is often a sign of stress which often occurs with a poor lens fit, possibly as a response to hypoxia or the mechanical effect of the lens.(161) Conjunctival injection has also been found to accompany corneal edema.(162)

Corneal epithelial staining has also been shown to occur under conditions of corneal hypoxia and may be worse with acute hypoxia.(163) Polse and Mandell have reported that corneal stippling may result from advanced corneal edema.(92) O'Leary et al noted that cell damage and/or necrosis was much less likely to occur if cellular swelling does not occur. They observed no epithelial staining in their human subjects after six hours of anoxia. They also were unable to measure any significant increase in thickness of the corneal epithelium and concluded that no staining would be expected since no swelling occurred.(154) Bergmanson, using histopathological analysis, has demonstrated that with epithelial edema the fluid is primarily between the cells and very little appears to actually enter the cells. The edema results in a fragile epithelium which in turn may lead to sloughing or loss of cells and subsequent superficial punctate staining.(157)

Corneal striae appear as small vertical or near vertical lines occurring in or near Descemet's membrane. Although they are most commonly associated with inflammatory, traumatic, or degenerative corneal conditions, they have been observed with hydrogel contact lens wear. These lines usually appear four to six hours after lens wear begins and resolve within two hours of lens removal. It has been suggested that these striae represent folds in Descemet's membrane that result from corneal edema.(164,165) In a 1976 study, Polse and Mandell were able to experimentally produce striae by depriving the anterior corneal surface of oxygen and therefore inducing edema. They concluded from their study that corneal striae accompanying gel lens wear are caused by corneal edema which is a result of atmospheric pressure deprivation. Also, as little as 6 per cent corneal edema can cause striae and therefore the presence of striae indicates corneal swelling of 6 per cent or more.(126)

Contact Lens Oxygen Ratings/Predictors of Corneal Response to Lens Wear

There are three methods that have been developed to predict or determine whether enough oxygen is allowed to pass through a contact lens to satisfy the cornea's metabolic requirements: equivalent oxygen percentage (EOP), a short-term biologic index reflecting the effect of lens wear on corneal oxygen demand; Dk/L, a physical measurement of the oxygen transmissivity of a lens; and pachometry, a physiologic measurement of the corneal swelling response to lens-induced hypoxia.(95,166) EOP and Dk/L values are considered predictive values of the cornea's response to a particular lens, while pachometry reflects the actual response of the cornea after wearing a particular lens.(166)

EOP

Equivalent oxygen percentage (EOP) was first introduced by Hill(167) using a technique developed by Hill and Fatt(100) and is a measurement of the corneal oxygen uptake after a standard period of lens wear. Thus, it indirectly gauges the oxygen transmission properties of a contact lens.(168)

When a contact lens is placed on the eye, it reduces the oxygen tension of the precorneal tear film in proportion to its ability to transmit oxygen. This reduction in precorneal tear film oxygen tension causes a reduction in corneal oxygen tension which Hill has termed "oxygen debt". Lenses that allow less oxygen to pass will cause greater "oxygen debt" or oxygen demand by the cornea after the lens is removed. This oxygen debt is measured by placing an oxygen-sensitive (polarographic) electrode directly on the cornea after the contact lens has been removed. Oxygen then diffuses from a polyethylene membrane which acts as a tiny oxygen chamber that is placed over the end of the polarographic electrode. The rate at which the oxygen is taken up by the cornea is inversely proportional to the precorneal oxygen tension that existed when the contact lens was on the eye.(169)

EOP is expressed on a scale of 0% to 21% with 0% indicating no oxygen permeability and 21% indicating a lens that is completely permeable to oxygen. A lens of a particular material can be tested at various thicknesses and the EOP value found for each thickness plotted to give an EOP curve. Several different materials can be tested and graphed in this manner allowing an easy comparison of the oxygen quantity transmitted by contact lenses of different materials and thicknesses.(95,170) Roscoe and Wison have found a strong correlation between oxygen transmissibility and equivalent oxygen percentage values. This shows that both of these facotrs are useful in predicting the oxygen tensions across the tear-epithelial interface during contact lens wear.(170)

Dk/L

Dk/L is the transmissibility of a contact lens and describes the ability of the lens to transmit oxygen. It is determined by physical measurement and is independent of actual lens wear. This value allows the manufacturer and the practitioner to predict the ability of the lens to meet the minimum corneal oxygen needs before the lens is even fitted.(166) These measurements are made by placing the lens over a polarographic electrode that is set-up in such a way as to allow only the oxygen that passes through the lens to reach the electrode. Materials that are less permeable to oxygen would result in lower readings. Also, lenses made of the same material but of varying thickness would result in different readings since oxygen permeability of a material is thickness dependent, i.e. thicker materials provide more resistance to the flow of oxygen.(85,132,171)

Transmissibility (T) is defined by equation 2:

2. T = Dk/L [expressed as 10(-9)(cm/sec)(mlO2/ml X mmHg)]

The Dk value of a material is defined as its permeability, which is the product of the diffusion coefficient (D) of the material and its solubility constant (k) as measured in a laboratory. The Dk is temperature dependent and is expressed in units of 10(-11)(cm2/sec)(mlO2/ml X mmHg). L is the thickness of the material.(172)

Oxygen permeability (Dk) is an intrinsic quality of a material which describes how oxygen molecules will act within the material and therefore each material has only one Dk value under constant conditions. Oxygen transmissibility (Dk/L), however, is an extrinsic quality of lenses that varies with the thickness (L) of the lens and therefore each lens may have many values. Dk/L gauges how effectively a given lens allows oxygen from the atmosphere to reach the cornea.(166) Dk is determined first determining the Dk/L of a material and then multiplying the Dk/L by L.(95)

One common error in determining Dk/L values is the use of only the center thickness value of the lens in the calculations. Since lenses are not typically uniform thickness, this can result in an erroneous value for the Dk/L of a particular lens.(95) Correction factors have been calculated to determine the average thickness of a lens which result in a more accurate Dk/L value for a specific contact lens.(173,174)

Several investigators have attempted to determine the minimal Dk/L values required to avoid or minimize corneal edema. Fatt and St Helen reported that a Dk/L of 6.7 X 10(-9)(cm/sec)(ml02/ml X mmHg) was required for daily wear and 23 X 10(-9)(cm/sec)(ml02/ml X mmHg) for overnight wear for normal corneal function.(132) Sarver et al. determined that a Dk/L of 20.0 X 10(-9)(cm/sec)(ml02/ml X mmHg) is the minimum value required for zero edema in the open-eye daily soft lens wear for the average patient.(80) Holden and Mertz have determined that a Dk/L of 24.1 X 10(-9) (cm/sec)(ml02/ml X mmHg) is the critical Dk/L during open eye soft lens wear to avoid corneal edema,(175) while the soft lens Dk/L required to limit overnight swelling to 4% (the expected level of edema overnight without lens wear) (176) was found to be 87.0 X 10(-9)(cm/sec)(ml02/ml X mmHg). This second value was very close to those subsequently found by O'Neal et al. and Andrasko.(149,177)

Pachometry

Measurement of the corneal thickness with a pachometer is considered the most useful index available for evaluating the physiological response of the cornea to contact lens wear.(178) If done correctly, the test can detect small levels of corneal edema that are not evident through visual acuity assessment or slit-lamp examination.

The main advantage to pachometry is that it shows the actual effect of lens wear on corneal physiology, whereas EOP and Dk/L values are predictors of corneal response to lens wear.(166) According to Ehlers and Hansen,(179) the pachometer is the most reliable instrument for measuring corneal thickness at the present time. The apparent linear relationship that has been demonstrated between corneal thickness and corneal hydration(123) has justified the use of corneal thickness measurements as an indicator of corneal hydration.(130) As explained in more detail above, corneal swelling occurs when the cornea is deprived of sufficient oxygen to carry on its normal metabolic function.(108,109) It has also been demonstrated that change in corneal thickness is inversely related to the average oxygen transmissibility of a contact lens. (147,175,180) Measuring the corneal swelling response to a contact lens may allow for evaluation of long-term contact lens compatibility in a relatively short period of time,(155) since the corneal response to a contact lens placed on the eye often begins within one-half hour of lens insertion and generally peaks within three hours. (181)

Blix is given credit for making the first measurements of corneal thickness in living eyes in 1880.(182) To make these measurements, Blix designed an apparatus consisting of two horizontal microscope tubes with optical systems of equal power and set to converge at an angle of approximately 40 degrees to a point in front of the tubes. Adjusting the tubes so that the image of the front surface reflection of the cornea through one microscope and the image of the back surface reflection through the other were properly positioned, an apparent distance between the surfaces was determined. The real distance was calculated from the radius of curvature and the index of refraction of the cornea.(182)

In 1948, von Bahr made several modifications to the principles used by Blix that is the basis for the modern day pachometer. Over the years, several modifications and improvements have been made to von Bahr's instrument resulting in the modern Haag-Streit pachometer commonly used today.(183,184) An in-depth description of the optical system of the Haag-Streit pachometer is included in the Methods and Materials section.

Several important modifications have been made to the Haag-Streit pachometer over the years. Mishima and Hedbys added two small lights which help to ensure that measurements are made perpendicular to the anterior corneal surface.(185) Mandell added a central light between these alignment lights to aid in patient fixation.(118) Binder in 1977 and Stevenson in 1989 described systems using optical pachometers interfaced with micro-computers. These instruments were described as easy to use and gave repeatable results with a high degree of accuracy under conditions where the observer has been properly trained. The speed with which measurements can be made, recorded, and analyzed make these instruments advantageous when large populations or many readings are required.(186,187)

Since the measurements obtained using optical pachometry depend on the precise alignment of a fine image, Hirji and Larke suggest considerable practice is required before reliable readings can be achieved.(188) The standard deviation for readings by a trained observer has been reported to be between 0.006mm while the untrained observer's is closer to 0.032mm.(189) Others have reported similar standard deviations in their studies where corneal thickness measurements were made.(179,190) Some of the sources of measurement error while making optical pachometry readings include poor image resolution, misalignment of the corneal reflex, observer fatigue,(130) lack of a consistent endpoint criteria by the observer,(191) inconsistent slit-beam width(192), instrument calibration,(193) inconsistent focusing of the corneal reflections,(194,195) and eye movement (unsteady fixation) by the subject.(196) Crook has suggested the use of fluorescein to stain the tear film as an aid in overcoming the inability to see when alignment is correct. (197)

Average corneal thickness values obtained by various investigators using the optical pachometer are shown on Table 5.

VISUAL ACUITY WITH CONTACT LENSES

Frequently, patients wearing contact lenses are able to achieve good Snellen visual acuity levels in the examination room but still complain that their vision is variable or even unsatisfactory in the outside world even with a well fitted lens. Pointer feels that quite often, the visual disturbances described by the soft contact lens wearer are too subtle to be detected by conventional optometric acuity charts.(198,199) Wechsler, however, found that soft lens wearers frequently were not able to read the visual acuity chart (Snellen) as well as with their spectacles, even when corrected for any residual astigmatism. He also reported that some hard lens wearers showed a decrease in visual acuity but the majority had no measurable change in visual acuity between their lenses and spectacles.(6) Sarver also noted that visual acuity achieved with hard contact lenses was not significantly different from those achieved with spectacle lenses.(200) Bernstein and Broderick used contrast sensitivity function (CFS) measurements to compare vision with contact lenses to vision with spectacle correction. They found no significant difference between the CSF's for the two types of correction and also found that there was no change in CSF over time with the soft contact lenses.(201) These findings are in conflict with earlier studies(6,205) but, as Bernstein and Broderick suggest, may indicate an improvement in the quality of soft lenses in recent years.

Carney states that there are two factors that govern the quality of vision with a contact lens: (a) the fit and movement of the lens, and (b) the adequacy of the optics. Possible mechanisms accounting for vision loss under these circumstances may include lens induced corneal changes, such as edema or distortion due to improper fit, uncorrected refractive error such as residual astigmatism, a poor lens surface caused by deposits, and the use of lens parameters or materials that are inappropriate for the patient. Fit and movement considerations are especially important with soft toric lenses which must be properly oriented and stable to achieve good visual acuity.(203)

Keeney and Shrader have discussed the kinetic (variable) visual disturbances that may occur during contact lens wear. They may be generated optically and/or mechanically. Examples include vertical displacement of the image during blink due to elevation of the lens by the lid (especially with rigid lenses), excessive tearing, optical aberrations from pupillary diameter exceeding lens optic zone diameter, and contour or edge blur of images due to epithelial edema caused by prolonged lens wear. Altered blink pattern (decreased blink rate) may occur during increasing task difficulty or visual concentration which may lead to lens surface drying, possible lens dehydration, and hypoxia. Dehydration blur may result from decreased blinking or lens wear in a drafty environment, particularly with high (55 to 79%) water content lenses.(204)

Pointer et al. believe that contact lens wearers learn to compensate for some of the visual disturbances that may occur with contact lenses by learning to prolong their viewing time and confine their eye-blink activity to the least detrimental frequency. This may bring about a mechanical adjustment to the optics of the eye-contact lens system and enhance visual acuity.(199)

Recently, the use of high and low contrast LogMAR acuity charts have been demonstrated to be a benefit in assessing the subtle visual acuity changes that occur with contact lenses.(205) Guillon and Schock measured the visual performance of soft contact lens wearers using LogMAR charts of two different contrasts (92% and 6%) and found that they were highly sensitive at detecting differences in visual acuity between lens types that were associated with differences in clinical acceptance and reliable at reaching similar conclusions for differences between corrections, even when used by different investigators on independent subject groups. (206)

THE BAILEY-LOVIE LogMAR VISUAL ACUITY CHART

In 1976, Bailey and Lovie introduced a new design for a visual acuity letter chart. This chart incorporated several design changes as compared to earlier visual acuity charts. The letters are said to be of almost equal legibility. Each row has the same number of letters, five per row. The spacing between each letter is equal to one letter width. The spacing between rows of letters is equal to the height of the letters in the smaller (lower) row. The size progression of the letters follows a geometric progression whose ratio or multiplier is equal 0.1 log unit or 1.2589. The chart is designed for testing distances of 6 meters. At that distance, the largest letters have stroke widths subtending 10 minutes of arc, the smallest letters have stroke widths subtending 0.5 minutes of arc, which gives a visual acuity range measurable from 20/200 to 20/10. Fourteen rows of letters are used. The scale notation at the side of the chart gives visual acuity ratings as the logarithm of the minimum angle of resolution (LogMAR) which is the logarithm to the base 10 of the angular subtense of the stroke widths at 6 meters. The chart size is 80cm high by 75cm wide.(207)

Nonstandard test distances can be used with this chart design since it has essentially equivalent test tasks and a logarithmic letter size progression. A scale at the bottom of the chart provides the correction factor which is added to the subject's score to adjust for nonstandard test distances. A table is also available that allows for conversion of LogMAR to 6-m Snellen notation. (Table 6)(207)

Another feature of the LogMAR visual acuity chart design is that an interpolated LogMAR score can be created since there is a 0.1 LogMAR unit between each line and each line has five letters. A LogMAR value of 0.02 can then be assigned to each letter of a line. By scoring 0.02 for each letter read correctly on the entire chart and adding these scores together, a single score is created which is a reasonable estimate of the LogMAR score for that eye at that particular time. This allows for easier statistical testing for visual acuity changes that may occur over time.(208)

The major advantage of the LogMAR visual acuity notation and the Bailey-Lovie chart design is that it provides an accurate and rapid method to measure visual acuity which is reproducible and in a format that facilitates quantitative data analysis.(208,209)

SOFTPERM CONTACT LENS/BENEFITS & CONCERNS IN THE AVIATION ENVIRONMENT

The Softperm contact lens was introduced by Sola/Barnes-Hind in April of 1989. This lens is unique in that it has a rigid gas permeable center and a soft hydrophilic skirt. The lens is not made by simply gluing together the two materials to form the lens but instead is made from a single button that contains both the rigid gas permeable phase and the soft hydrophilic phase. During the production process, the two materials are cross-linked so that there is an interweaving of the center and skirt materials forming a narrow transition zone. (Fig. 4) The button is then lathe-cut and polished in the dry state, then hydrated to form the Softperm lens with its two distinct phases.(210)

By its design, the Softperm lens may offer the crisp and stable vision of a rigid lens while having the comfort of a soft lens. The low water content of the skirt may be a benefit to dry eye patients or those working in dry conditions.(210) Dubow and Vrchota have fit over 100 patients with the Softperm lens and have found it to be very beneficial for athletes with astigmatism who require stable acuity, patients who have problems with drying hydrogel lenses, patients who wear RGP lenses and are bothered by dusty conditions, and those whose soft toric lenses are not providing clear or stable visual acuity. They also have found that the Softperm lens works well for those who have astigmatism but are near plano in the other meridian.(211)

Walker, in a case study of the Softperm lens, listed the following advantages of this lens design: (a) resists airborne debris, (b) does not dislodge, (c) stable vision, no rotational acuity problems as with soft torics, (d) excellent visual acuity for astigmats, (e) good comfort, (f) physiologically sound contact lens materials and design, (g) resistant to environmental influences and surface drying.(212)

The advantages of the Softperm lens design noted above make it a logical choice for pilots who require crisp, stable vision and must wear a lens that does not dislodge easily, is not prone to foreign body entrapment, will not dehydrate significantly, provides good comfort, and is physiologically safe.

A potential concern with the Softperm lens in the aircraft environment is its low Dk value [14 X 10(-11)]. Although this may be sufficient to allow safe wear at normal oxygen partial pressures, at low oxygen partial pressures such as those experienced in aircraft at high altitude, this lens may not provide enough oxygen to the cornea to maintain normal metabolic function. To meet Holden's suggested minimum oxygen transmissibility value to avoid corneal edema, this lens would have to be no thicker than 0.06mm.(175) Although it is made very thin, the normal thickness of the lens is 0.08mm to 0.16mm and therefore would have a Dk/L value below the suggested value of 24.1 X 10(-9)(cm/sec)(mlO2/ml X mmHg).

A second concern is the possibility of lens flexure due to the thinness of the rigid central portion. Any flexure may result in residual astigmatism thus providing less then optimum acuity. This problem has been reported in the literature.(211,213,214)

Despite these concerns, the Softperm lens appears to have several advantages over other designs and warrants evaluation of its potential use in the aircraft environment.

CHAPTER III

METHODS AND MATERIALS

Subject Eligibility and Selection

The study population consisted of thirteen individuals, ten males and three females, who volunteered to participate in the study. All potential subjects were evaluated prior to acceptance into the study to ensure that they met the study criteria and were free of ocular pathology. Only those who met the requirements and were found to have no ocular condition that contraindicated safe contact lens wear were selected to participate in the study. Initially, fifteen subjects were selected to participate in the study. One subject was dropped due to unsatisfactory lens fit and a second subject withdrew due to his inability to handle the lenses. Subjects were required to be between the ages of 18 and 45 in an attempt to match the age range of the majority of actively flying military aircrew members. The actual age range for the study participants was 21 to 39 years of age with a mean age of 25.5 years. Both previous contact lens wearers and non-lens wearers were allowed to participate in the study. Only one of the thirteen study participants had not worn contact lenses prior to the study. Subjects were required to have normal systemic health and not to be using any medications known to cause dry eye or other ocular side effects. A Snellen visual acuity of 20/20 or better with spectacles was desirable and all but one subject met this criteria. That subject had 20/40 in her right eye due to a retinal detachment that had occurred in 1984. The study protocol limited participation to those having 0.75 to 2.25D of astigmatism with corneal toricity and refractive astigmatism nearly equivalent. Subjects were required to achieve at least four hours of successful contact lens wear per day before any testing was performed. Most subjects were able to achieve seven to eight hours of comfortable lens wear per day with the study lenses. A minimum visual acuity level with the test lenses was not established in the protocol since this was one of the areas to be evaluated during the study.

Most of the participants in this study were students and faculty of the O.S.U. College of Optometry and therefore had received comprehensive eye exams within the past year. Full exams were not repeated on these individuals and information was used from their clinical records to determine eligibility for the study. Subjects who were not previously seen in the Optometry Clinic were given comprehensive eye exams before participating in the study. Subjective refraction, keratometry readings, and a slit lamp exam were performed on each subject before the study lenses were fitted. Appendix A provides each subject's history, refraction, keratometry readings, and slit lamp findings as well as the contact lens parameters used for the subject.

A signed statement of informed consent was required from each subject. The informed consent outlined the nature and purpose of the study, explained the subjects rights as well as their responsibilities while participating in the study, and described the potential risks involved. Female subjects were required to initial a statement stating that they were not pregnant and that they were to inform the investigator immediately if they become pregnant. Signing the consent form constituted enrollment in the study and an understanding of the potential risks involved.

MATERIALS AND METHODS

Each subject in this study was fitted with a pair of Sola/Barnes-Hind Softperm contact lenses. This contact lens design is unique in that it is made from a two-phase material known as Synergicon A that is formed by co-polymerizing a soft (hydrophilic) outer material to a rigid gas permeable center material which is then lathe-cut into a finished, two-phase lens. The Softperm lens therefore, consists of a rigid gas permeable center with a soft, hydrophilic outer skirt. The rigid gas permeable portion of the lens is made of Pentasilcon P which has a Dk value of 14 X 10(-11)(cm2/sec)(mlO2/ml X mmHg). The hydrophilic skirt portion of the Softperm lens is made of a HEMA-based hydrogel material with a water content of approximately 25%. The overall lens diameter is 14.3mm while the RGP center portion is 8.0mm in diameter and has a 7.0mm optical zone. Center thicknesses range from .08mm minimum to .28mm maximum. The Softperm lens is FDA approved and has been on the market since April 1989.(210,211,212,213) Appendix B provides further information on the Softperm lens and the parameters that are available.

The lenses were fitted using the manufacturers guidelines that are provided in the Softperm Lens Professional Fitting Guide. Part of this guide has been reproduced in Appendix B. Fluoresoft (tm, Holles Laboratories Inc.), a macro-molecular fluorescein solution, was used to evaluate the cornea to base curve relationship during the fitting of the lenses. The Concept lens care system was provided to the subjects for cleaning and disinfecting their lenses during the study.

The simulated aircraft environment was achieved by circulating rarefied, dehumidified air through modified swimming goggles. The goggles were fitted on each side with one inlet tube on the top and one outlet tube on the bottom which allowed the air to pass over the eye. (Plate 1) The rarefied air was provided by a storage cylinder that was certified to be 13.90% oxygen with the balance nitrogen. (Plate II) This oxygen level simulated the partial pressure of oxygen (105.6 mm Hg) at an altitude of approximately 11,500 feet mean sea level (MSL). (Fig 3.) The rarefied air was dehumidified by passing it through two acrylic tubes that were filled with 10-20 mesh Drierite desiccating crystals ($CaSO4$). The relative humidity of the air entering and exiting the goggles was continuously monitored by two Markson RH Pens (Plate III) that were placed in acrylic tubes on the inlet and outlet sides of the goggles. The Markson RH pen is calibrated at the factory under controlled conditions and tested over a wide humidity range. According to the user's guide provided by the manufacturer, the pen is accurate to within + or - 3% across its full measurement range of 0 to 100% relative humidity. Three of these pens were available for the study and were compared on two different occasions. Two of the pens read the same while a third consistently read 3% higher. The two pens that read the same were used in the study. The average relative humidity of the air entering the goggles was 2% while the relative humidity of the air exiting the goggles was 14.2%. The temperature of the air entering the goggles was at or near room temperature. Table 7 provides this data for each subject. Vinyl tubing was used to connect the components and hose clamps were used at critical or questionable fittings to prevent leakage. The final outlet tube was exhausted into a glass container of water which was constantly monitored by the subject to ensure that a positive pressure was maintained in the system throughout the experiment. (Plate IV)

The room that was used for this study measured 17 feet long by 9 feet wide by 8 feet high. Ambient room temperature and relative humidity was controlled by a dehumidifier, Sears Kenmore Model #106.855481, and a room air conditioner, Sears Kenmore Model #253.8781291, and monitored by a Labcraft Hygrometer/Thermometer. (Plate V) The hygrometer used to monitor ambient humidity levels in this room was found to read 10 to 12% higher than the Markson pens.

Visual acuity was measured using the Bailey-Lovie LogMAR (Logrithm Minimum Angle of Resolution) High (#4) and Low (#7) contrast visual acuity charts (National

Vision Research Institute of Australia, Copyright 1978). (Plate VI) The room lighting was provided by standard overhead fluorescent luminaires and was kept as consistent as possible for all visual acuity measurements throughout the experiment. The luminance levels were found to be 38.5 cd/mm for the high contrast LogMAR chart and 35.2 cd/mm for the low contrast logMAR chart when measured with the Pritchard photometer. The Bailey-Lovie logMAR visual charts were chosen over other methods of visual acuity testing for this study due to their ability to measure and score visual acuities accurately, and because the logMAR visual acuity scoring method allows arithmetic procedures such as regression analysis and parametric statistics to be applied legitimately to the scores.(209,215)

Slit lamp examination to assess lens fit, tear debris, lens debris, conjunctival injection, and corneal staining and to look for corneal striae was performed using a Nikon FS-2 slit lamp biomicroscope. Tables 8, 9, 10, & 11 shows the grading scales used to evaluate tear debris, lens debris, conjunctival injection, and corneal staining. Corneal epithelial staining was evaluated by touching a Fluorets (tm) Fluoroscein sodium BP (1mg.) strip, Smith & Nephew Pharmaceuticals Ltd., wetted with one drop of sterile isotonic buffered solution (Bausch & Lomb Eye Wash) to the superior bulbar conjunctiva, and then viewing the cornea through the cobalt filter of the biomicroscope.

Corneal thickness measurements were accomplished using an optical pachometer. The unit used for this study consisted of a Rodenstock RO2000SE slit lamp biomicroscope with a Haag-Streit mechanical pachometer model 9003589 mounted on it. (Plate VII) The pachometer had been modified by adding an electronic digital recorder to it that was connected to an Apple IIe computer that recorded each measurement, calculated the mean, and determined the standard deviation for each set of measurements taken. This data processing was accomplished through the use of Pachometry Analysis software (ATI, Columbus, Ohio, 1986). (Plate VIII)

The Haag-Streit pachometer uses a 10X image splitting eyepiece on the right ocular of the slit lamp biomicroscope to divide the corneal optical section that is observed through the microscope into an upper and lower half. Mounted in front of the right ocular is an attachment containing two glass plates, the lower fixed and the upper rotatable. The upper glass plate is connected to a movable arm that can be adjusted to vary the separation between the upper and lower halves of the optic section. The slit lamp beam is fixed at an angle of forty degrees with respect to the right biomicroscope ocular. The measurement of the corneal thickness is made by aligning the endothelial surface of the upper half of the optic section (the right edge) with the tear-epithelium surface of the lower half of the optic section (the left edge) by manually rotating the movable arm that is attached to the upper mirror. When this alignment is properly made, the displacement of the light beam by the rotatable glass plate is equal to the apparent thickness of the corneal optic section.(185) A potentiometer connected to the pachometer converts the mechanical position of the arm to an output voltage that is proportional to the angle between the mirrors required to properly align the optical sections and, thus, to the corneal thickness. This output signal is interfaced with the microcomputer system described above. The information is displayed on the computer screen and can be printed out as well.

Since each operator may choose a somewhat different endpoint when aligning the optical sections, it is necessary for each operator to calibrate the pachometer before taking any actual corneal thickness measurements. This is accomplished by taking measurements of PMMA lenses of known uniform thickness. Through this process, the Pachometry Analysis software generates a regression line that is a function of the operator's accuracy in measuring the thickness of these lenses. This regression is stored in the pachometry software program and allows all future measurements by that operator to be adjusted for the operator's measurement bias. A correction factor of 0.925 (cornea/PMMA = 1.376/1.49) is used to convert the lens thickness value determined by the pachometer to the actual lens thickness. Appendix F shows the calibration lenses and regression analysis used for all pachometry measurements in this study.

The fixation system used on this pachometer consists of eleven red light emitting diodes set in a pattern shown by Plate IX. The central fixation light and the light immediately above and immediately below the central light were used during all measurements in this study. The subject was asked to fixate on the central light while the measurements were being taken. The image of the central fixation light was used to ensure that the beam was vertically centered on the subjects cornea while the upper and lower lights on the were used to ensure that the slit lamp beam was positioned properly on the surface of the cornea during measurement.

For this study, a slit width of 0.2mm was used. The intensity of the slit lamp at its maximum setting was 5700 lux and all measurements were made with the lamp at its highest setting throughout the study. A magnification of

24X was used for all measurements.

Previous studies have shown that a trained observer can obtain repeatable optical pachometry measurements with a standard deviation of 0.006mm.(187,188) Factors that may affect the accuracy of measurements include, patient fixation, operator experience, alignment of the system, "noise" or error in the system, and proper focus of the slit lamp beam.(185,216) Average corneal index of refraction and corneal curvature are assumed when corneal thickness is determined by this method, but the induced error because of this is considered negligible for in vivo measurements.(216)

In a recent study by Cox, he found that corneal thickness measurements taken within minutes of each other could vary by as much as 0.02mm due to changes in patient fixation and observer alignment. Cox proposes that taking the average of two groups of five readings, rather than taking the average of one set of five or ten readings as is commonly done,(109,187) may be a more repeatable and more reliable estimate of the corneal thickness.(217) For this study, two groups of six readings were taken and averaged together to determine the corneal thickness. Any set of readings with a standard deviation greater than 0.018mm was repeated.

The percent change in thickness was determined using equation 3:(176)

$$3.\ \%\ \text{change} = (T.A.) - (T.B.)/T.B.\ \times 100$$

where T.A. = Thickness after and T.B. = Thickness before treatment.

No baseline readings were taken during this study until the subjects had been awake for at least two hours to ensure that the corneas had sufficient time to recover from normal overnight swelling.(176,218) Also, no contact lens wear was allowed eight hours prior to the initiation of the study to assure that no corneal edema secondary to contact lens wear could effect the measurements.

PROCEDURES

After determining that a subject was eligible to participate in the study, he was fitted with the Softperm lens. The fitting guidelines provided by the manufacturer were followed during all fits, and refits were accomplished when a lens was determined to fit or perform poorly. Four subjects (six eyes) required refitting to acquire a satisfactory fit. The majority of these refits were due to the lens being fitted so that there was significant apical touch. One lens was found to have distorted optics. Once it was determined that an optimal fit had been attained, the patient was allowed to adjust to his lenses for a minimum of one week before any testing was accomplished.

Three different evaluations were made on each eye of each subject in this study. In addition, a questionnaire was completed by each subject after the third treatment and at the conclusion of the study which allowed for subjective evaluation of the Softperm lens.

The first evaluation performed on the Softperm lens was to assess its ability to fully correct the astigmatic refractive error of the subject. To accomplish this, visual acuities were taken using a standard Snellen chart and then over-refractions were performed to determine the amount of residual astigmatism. A summary of the refractive cylinder, corneal toricity, calculated residual astigmatism, and measured residual astigmatism for each subject is found in Table 12. The predicted or calculated residual astigmatism was determined by taking the difference between the eye's corneal plane cylinder and the corneal toricity measured with the keratometer. Table 13 shows the calculated flexure, which was determined by taking the difference between the over-refraction cylinder and the predicted residual astigmatism. The thickness of the contact lens and the amount of lens flexure as a percentage of the corneal toricity is also provided in Table 13.

The second part of this study involved evaluating the Softperm lens in a normal environment. The objective of this phase of the study was to determine whether any corneal changes occurred while wearing the Softperm lens in the "normal" environment over a period of two hours. For study purposes, normal was intended to mean an environment that has near normal atmospheric pressure (155mm/Hg) and a temperature and humidity range that would be considered typical for a large public building. In an attempt to keep these variables somewhat similar throughout the study, the subjects were asked to remain in the building for the duration of the testing. Building temperature and humidity were measured at the start of the testing period for each subject. The average temperature in the building for all test days was 75.3 degrees F with a range of 69 to 80 degrees F. The average humidity was 47% with a range of 30% to 64%.

The testing sequence for this part of the study started with pachometry measurements on each eye to establish a baseline corneal thickness value. Pachometry was followed by slit lamp biomicroscopy to evaluate and grade the extent of conjunctival injection, and tear debris. Fluorescein was instilled in each eye to evaluate the cornea for staining. The cornea was divided into five zones and staining assessed and graded in each zone. (Fig. 5) The cornea was also checked for striae. Next, the subject was instructed to insert their Softperm lenses. After the second lens was in place, the two hour test period began. It should be noted that the eyes were not irrigated before the lenses were inserted since it was speculated that the irrigation process may induce mild corneal trauma that would effect the results of the study.

After ten to fifteen minutes to allow for lens stabilization, LogMAR visual acuities were measured monocularly starting with the right eye, first reading the high contrast chart, and then the low contrast chart. This sequence was repeated for the left eye. Next, the lens fit was evaluated by observing amount of movement with normal blink and whether the lens was centered on the cornea or not. The amount of lens debris (debris trapped under the contact lens) was also graded at this time. The subject was given a copy of questionnaire #1 (Appendix G) and allowed to leave the exam room until two hours of lens wear was achieved, at which time they were to return for re-evaluation. The post-wear testing sequence began with visual acuities, followed by slit lamp biomicroscopy to evaluate lens fit, tear debris, lens debris, and lens fit. Next, the contact lens was removed from one eye only and pachometry measurements were made on that eye before lens removal and thickness measurement of the fellow eye. Readings were made as quickly as possible after lens removal to limit the possibility of corneal deswelling that could alter the thickness measurements. After the pachometry readings were made on both eyes, slit lamp biomicroscopy was again performed to look for corneal striae. Fluorescein was then instilled into each eye and the extent of corneal staining was assessed and graded. The subject was then asked to turn in Questionnaire #1, then allowed to leave.

The third phase of this study involved evaluating the Softperm lens in the simulated aircraft environment. As discussed earlier, this environment was achieved by having the subject wear goggles through which rarefied, dehumidified air was passed. (Plate X) Only eleven of the thirteen subjects were evaluated during this phase of the study because the gas cylinder ran out of gas shortly after subject number eleven was evaluated.

The purpose of this part of the study was to determine if significant corneal changes such as corneal edema or staining occurred when the Softperm lens was worn at a simulated altitude of 11,500 feet mean sea level. Also of interest was the effect that this low oxygen, low humidity environment might have on the fitting characteristics of the lens and whether visual acuity through the contact lens was diminished after exposure of the eyes to the environment.

The sequence used in the third part of the study was identical to the sequence used in the second part except that the subject was required to put on the goggles and remain in the testing room for two hours. The subject was allowed to read or work on various other tasks during the two hour period. At the one hour point, lens fit, tear and lens debris, and conjunctival injection were assessed and graded by observing the eyes through the goggles with the slit lamp microscope. During part three of the study, the patient was asked to fill out Questionnaire #2 (Appendix G) which allowed him to make subjective comments concerning lens comfort and vision changes during the two hour test period. After completing the questionnaire, testing was complete for that subject and he was released from the study.

STATISTICAL ANALYSIS PROCEDURES

When doing statistical analysis on eyes, an issue that often arises is whether the two eyes of the same subject can be treated as independent or are they dependent in some way. Since the correlation between the two eyes is often quite high, which would bias data that treats them as if they were independent toward statistical significance, Barbeito and Herse advise using all right eyes of subjects, all left eyes of subjects, or an average of the right and left eyes of the subject when doing a t-test(219).

For the statistical analysis found in this report, one eye from each subject was randomly selected by the flip of a coin (Table 14). These same eyes were used as the data points for the paired t-tests done on both the corneal thickness measurements and the visual acuity measurements. One eye from each of the thirteen subjects who participated in normal environment phase of the study was used when determining whether significant corneal thickness changes or visual acuity changes occurred during that part of the study. This same eye was used in the statistical analysis of the eleven subjects who went on to participate in the simulated aircraft environment phase of the study. When the data from the first environment was compared to the second, again the same eyes for the eleven subjects who participated in both treatments were used.

Statistical analysis (paired t-tests) were done using the Minitab Statistical Software program. A significance level (alpha level) of 0.05 was chosen to determine the statistical significance of a test.

CHAPTER IV

RESULTS

The main objective of this study was to evaluate the performance of the Softperm contact lens in a simulated aircraft environment. To do this, two similar test procedures were performed in two different environments. The first environment was considered "normal" since no modification to the temperature, humidity, or oxygen level was made. In the second environment, humidity and oxygen levels were reduced to simulate the aircraft environment. During each procedure, the cornea was examined for signs of hypoxic stress, including evaluating for changes in corneal thickness, corneal staining, striae formation, and bulbar conjunctival injection. Also, visual acuity was assessed before and after each treatment to see if any measurable change had occurred. Lens fit was also monitored to see if either treatment caused any significant changes in lens movement. Tear and lens debris were graded before and after each treatment and then compared to see if either treatment had an effect on these.

A second objective of this study was to evaluate the Softperm lenses ability to correct astigmatism and provide adequate visual acuity. The subjects were also asked to provide a subjective evaluation of the vision and comfort they experienced with the Softperm contact lens.

Corneal thickness measurements that were taken before and after two hours of Softperm lens wear in the normal environment were compared. (Table 15) No statistically significant difference ($p = 0.46$) in thickness was found, which indicated that little or no stromal edema had occurred. (Table 16) When the corneal thickness measurements that were taken before and after two hours of lens wear in the simulated aircraft environment were compared, (Table 17) a statistically significant increase in corneal thickness was found ($p = 0.0027$) indicating that corneal swelling (edema) had occurred. (Table 18) When the corneal thickness changes found at the end of two hours of lens wear in the normal environment were compared to the corneal thickness changes found at the end of two hours of lens wear in the simulated cockpit environment, a small but statistically significant difference ($p = 0.024$) was found. (Table 19)

No statistical analysis was attempted on the corneal staining data that was collected. Instead, it was decided that only the number of subjects that showed a change in the staining grade after each treatment would be reported.

After two hours of Softperm contact lens wear in the normal environment, the number of eyes per total (13 right and 13 left) in each zone that had increased staining were, 9/13 right eyes and 10/13 left eyes in zone one, 10/13 right eyes and 9/13 left eyes in zone two, 4/13 right eyes and 7/13 left eyes in zone three, 5/13 right eyes and 8/13 left eyes in zone four, and 4/13 right eyes and 5/13 left eyes in zone five. (Table 20)

After two hours of Softperm contact lens wear in the simulated aircraft environment, the number of eyes per total (11 right and 11 left) in each zone that showed increased staining were, 8/11 right eyes and 7/11 left eyes in zone one, 6/11 right eyes and 5/11 left eyes in zone two, 3/11 right eyes and 2/11 left eyes in zone three, 4/11 right eyes and 4/11 left eyes in zone four, and 2/11 right eyes and 5/11 left eyes in zone five. (Table 21)

Reviewing Table 20 and Table 21 it appears that the majority of the staining that occurred was in zones one (central) and two (superior) of the cornea during both treatments. It is also apparent that the changes were greater in zone one. For the normal environment, 3/13 right eyes and 4/13 left eyes in zone one increased by 2 or more staining grades while nearly all other increases in staining reported for the other zones were an increase of 1 grade only. Similar results were found for the simulated aircraft environment where 4/11 right eyes and 4/11 left eyes in zone one showed an increase in 2 or more grades.

When attempting to compare the changes in staining that occurred during lens wear for the eleven subjects who were exposed to both treatments, no clear pattern could be found. Looking at zone one, only subjects one and five showed an increased staining response during exposure to the simulated aircraft environment as compared to the normal environment. The changes that occurred in the other four zones were nearly the same under both environmental conditions for all eleven subjects.. Subjects #2 and #3 had an increase of 2 or more grades in zone one during both treatments, the response to both environments being nearly identical.

No statistical procedures were used to evaluate changes in bulbar conjunctival injection noted during the two treatments. Again, only the numbers of eyes showing change are reported.

For the normal environment, 5 of the 13 right eyes and 8 of the 13 left eyes became injected or had an increase in the amount of injection of one grade level after two hours of lens wear. No eyes had greater than a one grade increase. All five of the subjects who showed an increase in the amount of injection in the right eye had an equal increase in the left eye, while three subjects had an increase only in the left eye. (Table 22)

After a two hour exposure to the simulated aircraft environment while wearing the Softperm lens, 10 of the 11 right eyes and all of the left eyes became injected or showed an increase in the amount of injection. Subject #9 increased by 2 grade levels in both eyes while all other increases were 1 grade level only. (Table 23)

Although bulbar conjunctival injection occurred or increased in both environments, more subjects became injected or showed an increase in injection after exposure to the simulated aircraft environment.

Statistical analysis of the high contrast LogMAR visual acuity measurements (Table 24) resulted in no statistically significant difference ($p = 0.61$) between baseline and post-treatment visual acuities during lens wear in the normal environment. (Table 25) The difference between low contrast LogMAR visual acuities (Table 26) were also found not to be statistically significant ($p = 0.25$) with a mean of -0.0185 log-units or approximately one letter improvement after two hours of lens wear. (Table 27) (Recall that each letter on the LogMAR chart is given a value of 0.02 log-units).

When high contrast LogMAR visual acuity after two hours of contact lens wear in the simulated aircraft environment was compared to baseline visual acuities, (Table 28) no statistically significant difference ($p = 0.20$) was noted. (Table 29) The mean change was +0.025 log-units which is approximately one letter decrease after the treatment as compared to before. The change in low contrast LogMAR acuity (Table 30) during this treatment was even less significant ($p = 0.87$) with a mean change of only 0.0036 log-units. (Table 31)

To see if there was a statistically significant difference between the changes in high and low LogMAR visual acuity after two hours of lens wear in the normal environment and two hours of wear in the simulated aircraft environment, a paired t-test was done using the data from the eleven subjects who participated in both parts of the study. For the high contrast LogMAR chart, a mean change of 0.038 log-units was found which is approximately a two letter decrease between the two treatments. (Table 32) This was not considered statistically significant ($p = 0.23$). Likewise, no statistically significant difference ($p = 0.32$) was found for the low contrast LogMAR visual acuity changes. (Table 33)

To evaluate the Softperm contact lens' ability to correct astigmatism, Snellen visual acuities and over-refractions were performed. (Table 34) Calculated residual astigmatism values were determined (assuming no lens flexure) from the refractive cylinder and corneal toricity values. (Table 12) Next, lens flexure was calculated using the predicted residual cylinder and the over-refraction cylinder. This allowed a comparison between lens flexure, corneal toricity, and lens thickness. (Table 13)

The amount of flexure ranged from a minimum of 0% (one eye) to a maximum of 100% (2 eyes) with three eyes showing flexure greater than the amount of measured corneal toricity. The average amount of flexure was 55% (not including the 3 eyes whose flexure was greater than the measured corneal toricity). The thin lenses flexed significantly on the more toric corneas such as in the case of subjects #5 and #11, and even on less toric corneas such as subject #7's. Flexure for the thicker lenses was quite unpredictable. (Table 13)

Residual astigmatism was observed in all but two eyes (subject #1), but no eyes had greater than 0.75D of residual astigmatism. Visual acuity through the lenses without over-refraction was 20/20 or better for all eyes except two which were 20/25 and 20/30. (Table 34) (The

20/30 eye was 20/25 best corrected due to a history of retinal detachment).

Subjective comfort and visual acuity were assessed using two questionnaires which were completed during each treatment. (Appendix G)

While wearing the Softperm lens in the normal environment, 2 subjects out of 12 reported no lens awareness while 5 out of 12 subjects reported only occasional awareness of the lens, and 5 out of 12 reported consistent awareness/slight discomfort. One subject reported consistent discomfort in one eye only. One subject failed to complete and return the form. Acuity during lens wear in the normal environment was reported as satisfactory or very satisfactory by 11 out of 12 subjects while one subject reported variable vision. (Table 35)

Subjective comfort while wearing the Softperm lens in the simulated aircraft environment rated as, occasional slight awareness by 5 out of 11 subjects and consistent awareness/slight discomfort by 6 out of 11. One subject reported consistent discomfort in one eye. (Table 36) Eight of the eleven subjects reported no noticeable vision changes while in the simulated aircraft environment while 3 reported slight vision changes. This was described as variable vision by 2 of these 3 subjects. (Table 37)

These subjective findings seem to indicate that the comfort of the lens was not affected by the simulated aircraft environment while subjective visual acuity may have been altered slightly.

The effect that the dry air in the simulated aircraft environment may have had on lens fit, tear film quality, and debris accumulation under the lens was also evaluated.

In the normal environment, 12 out of 26 lenses showed no change in movement after two hours of wear while 13 became tighter. Only one lens was considered looser after two hours of wear. In the simulated aircraft environment, 9 out of 22 lenses showed no change in movement, 10 out of 22 became tighter, and 3 lenses appeared to move more after being worn for two hours. (Table 38) No observable difference in the amount of lens movement between the two treatments was noted.

No increase in the level of tear debris was noted during lens wear in the normal environment, (Table 39) while one subject (both eyes) showed a slight increase (one grade level) during exposure to the simulated aircraft environment. (Table 40) This difference is not considered to be of any clinical significance.

An increase in the amount of debris under the lens was noted in five subjects out of thirteen (10 out of 26 eyes) during lens wear in the normal environment. (Table

41) Seven of the eleven subjects (13 out of 22 eyes) who were evaluated in the simulated aircraft environment had an increase in lens debris. Only one eye had more than one grade level increase which occurred during the simulated aircraft environment. (Table 42) This indicated a small increase in the amount of tear debris noted after the second treatment as compared to the first.

No striae were observed in any eye after two hours of Softperm contact lens wear in either the normal or the simulated aircraft environment.

CHAPTER V

DISCUSSION

Corneal swelling as a result of exposure to a hypoxic environment(91,108,109,110) and from contact lens wear (92,108,110,124) has been well documented. Measurable corneal thickness changes result from swelling (increased hydration) of the corneal stroma although corneal epithelial swelling may also occur. The relationship between corneal thickness and corneal hydration has been described by Hedsby and Mishima as a linear relationship.(123) The issue of epithelial swelling is still being debated but it is generally agreed that epithelial changes do occur during periods of anoxia that can lead to halos, glare, and visual acuity loss. (151,153,154)

The minimum oxygen level required to avoid corneal swelling has been studied by several investigators and the critical value revised (raised) after each of these studies.(108,109,110) Efron and Brennan have gone as far as suggesting that anything less than 20.9% oxygen will alter the physiological status of the cornea.(111)

In this study, the simulated aircraft environment that was created had a mixture of 13.9% oxygen and the balance nitrogen. This provided an environment equivalent to an altitude of approximately 11,500 feet where the partial pressure of oxygen would be 105.6mm Hg. This is well above the minimum level of 74mm Hg that Holden et al. determined to be necessary to avoid corneal edema.(110) Exposure to just this environment alone (no contact lenses worn) would not be expected to cause any significant corneal thickness changes and therefore, was not evaluated as part of this study. The effect of adding a contact lens to the cornea, which would further reduce the amount of oxygen available to the cornea, was a primary point of interest and was evaluated by measuring corneal thickness changes.

Calculations to determine the partial pressure of oxygen (oxygen tension or pO2) at the corneal surface are quite complicated. Fortunately, Fatt(132) has constructed a graph that allows one to determine the oxygen tension at the corneal surface under a lens of known Dk/L. This graph provides this information for both the open eye and the closed eye environment. (Figure 6) Using this graph, it can be determined that the pO2 for a Softperm contact lens [Dk = 14 X 10(-11)] with a thickness of 0.10mm [Dk/L = 14 X 10(-9)] would give an open eye pO2 at the cornea of about 40mm Hg while providing a closed eye pO2 of approximately 8mm Hg. In the both situations then, the pO2 at the cornea would be insufficient to avoid corneal edema at the level suggested by Holden et al. (74mm Hg), but would meet the pO2 requirements suggested by Polse and Mandell (11 to 19mm Hg) to avoid corneal swelling in the open-eye situation in a normal (pO2 = 155mm Hg) environment.(108)

Since the atmospheric pO2 created by the simulated aircraft environment was approximately equal to 100mm Hg, which falls very near the middle of the open eye (155mm Hg) and closed eye (55mm Hg) curves on the graph, extrapolation was used to estimate the pO2 at the corneal surface in the simulated aircraft environment with the Softperm lens on the cornea. Assuming an average center thickness of 0.10mm, which is it's reported thickness at -3.00D, the Softperm lens would allow a pO2 level at the cornea of approximately 18mm Hg when worn in the simulated aircraft environment. This level falls far below the pO2 suggested by Holden et al. and is within the range suggested by Polse and Mandell. Any lens much thicker than 0.10mm would fall below even the suggested range of Polse and Mandell. The reported thickness range of the Softperm lens is 0.08 to 0.28mm which would give a Dk/L range of 17.5 X 10(-9) to 5.0 X 10(-9) respectively.

Again, using Dr. Fatt's graph and extrapolating, the resulting pO2 range in the simulated aircraft environment would be approximately 23.0mm Hg to 3.2mm Hg for this center thickness range. Just as a comparison, the Hydrocurve II lens, which is approved for wear by USAF aviators, is reported to have a Dk/L of 22.7 X 10(-9) at a power of -3.00D. The pO2 at the cornea with this lens in the simulated aircraft environment would be approximately 33mm Hg while the pO2 in the normal environment would be about 72mm Hg, the latter value being very close to Holden et al.'s suggested pO2 value to avoid corneal edema. Sarver et al. evaluated five subjects wearing -3.25 to -3.37D Hydrocurve II lenses for three hours in both the open eye and closed eye environment and found no corneal thickness changes in the open eye environment but nearly a six percent increase in corneal thickness in the second environment.(80)

Using data from several other studies, Natsumeda and Fatt have formed a graph that relates changes in corneal thickness to pO2 at the anterior corneal surface.(99) Using this graph (Figure 7), one would not expect to find any corneal edema with the Softperm lens worn in the normal environment (40mm Hg at a c.t. of 0.10mm) using Polse & Mandell or Mandell & Farrell's suggested pO2 levels to avoid corneal edema, which are 11mm Hg to 19mm

Hg and 23mm Hg to 37mm Hg respectively. When the Softperm lens is worn in the simulated aircraft environment, however, the pO2 ranges from 3.2mm Hg to 23.0mm Hg (c.t. of 0.28 to 0.08mm). This corresponds to a corneal thickness change of 7.0% to 0% using the data line from Polse & Mandell's study and 6.75% to 0.75% using the data line from Mandell and Farrell's study.

Table 43 shows the summary statistics for the pachometry data collected during this study. The first group of data resulted from comparing the baseline corneal thickness measurements to the corneal thickness measurements found after two hours of Softperm contact lens wear in the normal environment. As might be expected from earlier studies and the discussion above, no significant difference in corneal thickness was found in this study after the Softperm lens was worn for two hours in the normal environment when compared to the baseline values.

The second group of data in Table 43 shows the statistics that resulted from comparing the baseline corneal thickness measurements to the 120 minute corneal thickness measurements after lens wear and exposure to the low oxygen, low humidity air. These results indicate that a statistically significant change (increase) in corneal thickness occurred after the Softperm contact lens was worn in the simulated aircraft environment.

After calculating the mean lens thickness of 0.11mm for the eleven lenses worn by the eyes that were randomly selected for statistical analysis, the average Dk/L value was determined and found to be 12.7 X 10(-9). Using Fatt's graph, (Figure 6) the pO2 at the anterior corneal surface with Softperm lens on the eye for this Dk/L value was determined to be 13mm Hg. Using Fatt's graph of Mandell and Farrell's data, (Figure 7) a corneal thickness increase of about 3.8% would be predicted.

The baseline average corneal thickness for the eleven eyes randomly selected for statistical analysis was determined to be 0.5114mm. The average corneal thickness after the Softperm lens was worn in the simulated aircraft environment for two hours was found to be 0.5328mm. (Table 44) Using Mertz's equation(176) to determine percent change in corneal thickness after a treatment, a value of 4.03% was calculated for the average increase in corneal thickness after exposure to the simulated aircraft environment. This value is in close agreement with that predicted by Mandell and Farrell's data and using Fatt's graph.

When the average corneal thickness change that was found after the Softperm had been worn in the normal environment for two hours was compared to the average corneal thickness change that occurred after two hours of lens wear in the simulated aircraft environment, again a statistically significant difference was found. (Table 43) This was not a surprising outcome considering that no significant swelling occurred after two hours of lens wear in the normal but statistically significant swelling occurred after two hours of wear in the simulated aircraft environment.

Although a statistically significant increase in corneal thickness was found after the Softperm lens was worn in the simulated aircraft environment, it should be pointed out that this amount of corneal swelling may not be clinically significant. Mertz reported in a 1980 study that the average amount of overnight swelling that occurred due to eye closure was 4.33%, which is greater than the amount of swelling reported in this study. It may be concluded that the amount of corneal swelling that occurs after two hours of Softperm contact lens wear in the rarefied, dehumidified, air environment is not of clinical significance, since it is less than the amount normally experienced by the cornea on a nightly basis.

It could be argued that two hours was not sufficient time to allow the full amount of edema that may occur while wearing a contact lens in the simulated aircraft environment to develop. This indeed may be the case, however, this test period was chosen because it represents the average duration of a typical fighter aircraft mission.(12) Also, several studies have shown that the majority of corneal swelling occurs in the first two hours after exposure to the hypoxic environment. (109,110,127,136) Although more swelling may occur beyond the two hour point, the increase is small compared to that which occurs initially and often reaches a maximum at three to four hours.

Corneal epithelial staining with fluorescein has been found to be associated with periods of corneal hypoxia and may be worse after periods of acute hypoxia.(92,163) The staining that results from hypoxia is thought to be due to epithelial edema. In epithelial edema, the fluid is thought to accumulate between the cells rather than within the cells resulting in what Bergmanson has described as a fragile epithelium. This fragile epithelium may more easily slough off during contact lens wear resulting in increased corneal staining.(157) O'Leary et al. found no corneal staining in their human subjects after six hours of anoxia and concluded that since no evidence of epithelial edema was observed, this was not an unusual finding since they believe that cell damage or death will only occur if epithelial edema has occurred.(154)

In this study, the majority of eyes showed increased staining after two hours of Softperm lens wear in both the normal and the simulated aircraft environment. No real trend could be found to indicate that more corneas stained after one treatment as opposed to the other. (Table 20 & 21)

One obvious finding was that the majority of corneal staining that occurred was in the central and upper zones after lens wear in both environments. There was a slightly greater number of corneas that increased more than one step on the grading scale in zone one after the two hour exposure to the low oxygen, low humidity environment than in the normal environment.

The increased staining that occurred in the superior part of the cornea (zone 2) may be due to the additional hypoxia that occurs with the upper lid riding over that part of the cornea.

As stated above, the most significant increase occurred in the central zone (zone 1) and there were slightly more corneas that showed a greater than one grade increase after lens were in the low oxygen environment indicating that the increased hypoxia may have caused slightly more epithelial disruption.

Another possible etiology of this corneal staining may have been the tear stasis and subsequent build-up of toxic by-products that can occur with this situation. Also, the altered tear chemistry that can occur during contact lens wear has been implicated as a cause of corneal epithelial staining during contact lens wear. (161,219) A comparison of the lens movement changes after two hours of wear and the amount of staining that occurred indicates that there may be a relationship between the lack of lens movement and the amount of corneal staining. This seems to hold true for both environments. Daniels et al. also noted a relationship between a tight fitting Softperm lens and corneal epithelial staining. They attributed this to the decreased tear pump action caused by the non-moving lens which resulted in epithelial compromise.(213)

Bulbar conjunctival injection has been reported to increase during exposure of the eye to hypoxic environments in several studies although very little has been written as to the etiology of this response.(20,27, 30,34) Conjunctival injection may be an indicator that corneal hypoxia and/or edema are occurring and, in the case of contact lens wear, indicate a refit is in order.(82,160,162) Brennan feels that the conjunctiva may be one of the better indicators of contact lens wear problems.(162)

Injection increased after two hours of Softperm lens wear in both environments, but as shown on Table 23, there was a much higher incidence of conjunctival injection after the subjects were exposed to the reduced oxygen and humidity levels. (21/22 eyes) These findings are in agreement with the studies reported above and help confirm that the conjunctiva may be an excellent indicator of corneal hypoxic stress. The conjunctival response noted in this study and others like it may simply be the conjunctiva's own response to the environment and have little or nothing to do with the hypoxic stress of the cornea. Certainly further research into this area is required before any firm conclusions could be made about conjunctival injection as an indicator of corneal stress.

Daniels et al. recently completed a clinical evaluation of the Softperm contact lens and reported some conjunctival and circumlimbal injection even with what they considered to be a normal fitting lens. They state that this occurs due to HEMA dehydration and flange steepening and advise the use of artificial tears to maintain proper hydration of the soft skirt.(214) If this is indeed the case, the low humidity of the aircraft environment may tend to dehydrate the hydrophylic portion even more thus aggravating this problem.

LogMAR high and low contrast (90% contrast and 8% contrast) charts were used to evaluate for visual acuity changes that might occur after wearing the Softperm lens in the simulated aircraft environment.(221) Recent studies have shown that these charts are more sensitive to subtle visual acuity changes that may not be found with more standard charts such as the Snellen visual acuity chart, especially when evaluating visual acuity changes with contact lenses or comparing the visual performance of contact lenses to contact lenses or to spectacle correction.(222,223,224)

Ho and Bilton evaluated low contrast visual acuity charts to see if they would be useful in differentiating between types of blur, specifically refractive defocus and diffusive blur. Refractive defocus refers to blur due to uncorrected refractive error while diffusive blur is a degradation in vision not correctable by altering lens power and is often due to diffusion of light. This may occur with nonhomogeneity of the optical media, diffusion by translucent particles, and irregular optical surfaces. Changes in the optical clarity of the cornea such as those that may occur with changes in epithelial or stromal hydration levels (edema) may lead to this type of blur.(222)

They found that visual acuity change between different contrast levels occurred only with conditions of diffusive blur and therefore, low contrast visual acuity charts provide a method to differentiate between diffusive blur and blur due to refractive defocus. Ho and Bilton also reported that the sensitivity of these charts may be increased by lowering the contrast level of the acuity chart. Guillon et al. also report that lowering the contrast or reducing the luminance increased the magnitude of any subtle changes in visual acuity that were found. (223)

Statistical analysis using the paired t-test showed no statistically significant difference between visual acuity before and visual acuity after wearing the Softperm lens in the normal environment for both the high and the low contrast charts. Likewise, no statistically significant difference in visual acuity was found for the simulated aircraft environment for both the high and the low contrast charts. (Table 44) These results are not too unexpected since no other significant findings were found that should greatly alter visual acuity during either treatment.

Three subjects did report that they noticed a subjective decrease in their visual acuity during the two hours in the low oxygen and humidity environment. When the visual acuities for those three subjects were reviewed, it was noted that two of the three did have a reduction in their visual acuity at the end of the two hours which occurred for both the high and low contrast charts. One subject's visual acuity decreased one full line on the high contrast chart in both eyes and one and one-half lines on the low contrast chart in the right eye while the left eye actually improved on the low contrast chart. This subject did not have any significant corneal staining or edema to account for the acuity loss.

As reported in the Chapter three, Methods and Materials, the luminance levels for the high and low contrast LogMAR charts were 38.5 cd/mm and 35.2 cd/mm respectively. These values are near the bottom end of the range Sloan suggests but much lower than the 85 cd/mm suggested by the Committee on Vision of the National Research Council.(225) Sheedy et al. have shown that visual acuity performance decreases with chart luminance. This may account for the slightly lower visual acuities attained with the LogMAR charts as compared to the Snellen acuities achieved during dispensing and follow-up visits.

The amount of lens flexure that was found during this study is certainly a concern with this contact lens design. The average flexure was found to be 57.6% of the corneal toricity. (Table 13) This is higher then reported by Blehl et al.(214) who found flexure of 25.8% when calculated by taking the difference in between the over-refraction cylinder and the predicted residual astigmatism. They found 30.9% flexure, however, when over-Ks were used as a measure.

This flexure most likely accounts for the high incidence of residual astigmatism that occurred during this study. As reported earlier, only one subject out of thirteen had no residual astigmatism in his over-refraction. No subject was left with more than 0.75D of residual astigmatism but several subjects had only 0.25D to 0.50D less residual cylinder than refractive cylinder indicating that the lens flexed nearly the full amount of their corneal toricity. Despite this residual astigmatism, only one subject had visual acuity less than 20/20 with the Softperm lens and that was in one eye only. (One subject was 20/30 best corrected in the right eye due to a retinal detachment that had occurred several years ago).

Several factors may contribute to the flexure that has been encountered with the Softperm contact lens. This lens has a thin center thickness which makes it less resistant to flexing than thicker rigid gas permeable materials. Also, the draping of the hydrogel skirt may add pressure to the rigid portion of the lens and cause it to flex even more on the toric cornea. The manufacturer also advises that the lens be fit steep which also tends to cause a rigid lens to flex more.(214)

The changes in comfort that occurred during lens wear was evaluated using two questionnaires that provided the participant an opportunity to subjectively grade changes that may have occurred over the two hour period of lens wear. This factor is important to the success of any contact lens but was of particular interest with the Softperm contact lens in the dry, rarefied air that the subject was exposed to. As discussed earlier, a pilot or aircrew member flying in a transport or cargo aircraft, or a fighter aircraft on a cross country flight, may be exposed to a similar atmosphere for periods of 6 to 8 hours. Any lens worn in this environment must be comfortable and must remain comfortable.

Eng has reported that flight attendants have long complained of eye irritation while wearing contact lenses in flight. Although the exact etiology of this discomfort is unknown, low humidity was thought to be the primary cause.(55) Jagerman feels that the low relative humidity in the aircraft cabin contributes to tear evaporation and, ultimately, to corneal hypoxia.(54) Ocular discomfort has been reported in the literature as being a complaint of those suffering from corneal edema which may support

Jagerman's theory to some extent.(160) Tear evaporation as the primary cause may be too simplistic, ignoring the effects of low oxygen partial pressure as a contributing factor or even the main cause of this discomfort.

The findings of this study indicate that there was very little significant decrease in the comfort of the Softperm lens after two hours of wear in the simulated aircraft environment when compared to lens comfort at the end of two hours wear in the the normal environment. (Table 35 & 36) This may be due to the fact that the hydrophilic portion of the lens has a very low water content which should minimize dehydration thus helping to maintain fit and comfort. However, lens fit changes did occur indicating that dehydration and subsequent tightening of the lens may have occurred.

Dehydration of hydrophilic lens materials when worn on the eye has been well demonstrated.(15,59,63) When exposed to dry air, the lens will dehydrate to a lower water content level which can steepen the base curve of the lens and tighten the fit.(61,62,65)

When the Softperm lens was evaluated for movement after two hours of wear and compared to the movement noted at baseline (15 minutes of wear), the lens movement decreased on nearly half of the eyes of the study subjects in both environments. There appeared to be no difference between the change in movement that was found after the normal environment and the change after the simulated aircraft environment. (Table 38)

The manufacturer reports a movement of only 0.25mm with blink as normal, so it would appear that this lens tends to move less then most soft lenses after settling on the eye. As noted above, however, there does seem to be a relationship between decreased lens movement and increased corneal staining. It is the author's opinion that this lens should move at least 0.25 to 0.50 mm with blink to maintain some tear exchange and avoid corneal compromise. In order to attain such a fit, the Softperm lens should be fit "steep" which often results in more movement of the lens but can also lead to more flexure.

Lens debris accumulation under the Softperm lens after two hours of wear was also evaluated. This is often an indication of tear stasis and accumulation of metabolic by-products that become trapped in the tear layer under the lens.(226)

An increase in the amount of lens debris was found in ten out of twenty-six eyes after two hours in the normal environment and thirteen out of twenty two after exposure to the low humidity and oxygen levels. (Table 41 & 42) This was not a surprising result considering the number of lenses that became tight during the two hour test period.

This decreased movement would result in tear stasis and the eventual accumulation of byproducts under the lens.

It was interesting to find, when comparing lens movement to lens debris accumulation in the normal environment, that the eyes that showed increased lens debris were not necessarily the same eyes whose lenses became tight after two hours of wear for either treatment. In fact, only three of the ten eyes that showed an increase in lens debris also had a tight lens fit after wearing the lens in the normal environment while five of the thirteen that tighten during the simulated aircraft environment showed an accumulation of lens debris. This suggests that debris accumulation under a contact lens may be related to factors other than decreased lens movement but, no speculation into what these factors may be will be made here.

An increase in tear debris has been reported in altitude chamber studies that expose the eye to low atmospheric pressures for periods of approximately four hours.(5,27,30) Increased tear debris has been attributed to lack of proper tear flushing or low humidity related dry eye syndrome due to rapid evaporation of the tears.(5)

In this study, no increase in tear debris was noted after two hours of lens wear in the normal environment. (Table 39) After two hours of exposure to the low oxygen, low humidity environment, only one subject showed an increased tear debris level. (Table 40) This is contrary to the studies noted above which reported nearly 100% of their subjects showed an increase in tear debris level. Possibly the difference in exposure time to the dry air may account for this discrepancy between the present study and earlier work in this area.

Although four subjects reached levels of corneal swelling sufficient to cause corneal striae during exposure to the simulated aircraft environment, no striae were observed during this study. (Table 17) One possible explanation for this could be the short duration of exposure to the low oxygen level. Polse and Mandell have demonstrated that striae often appear when the cornea is exposed to pure nitrogen for an average exposure time of two hours and thirty-seven minutes and after corneal swelling has reached a level of 6.4 to 8.5%(126). This is longer than the exposure time for this study and the eyes in this study were not subjected to total anoxia as they were in the above cited study.

One final item to discuss is the average corneal thickness value for all eyes in this study. Table 46 provides the mean and standard deviation values found for the baseline readings taken on all thirteen subjects (26 eyes) used during the normal environment evaluation of the

Softperm contact lens and the baseline readings for the eleven subjects (22 eyes) used for the simulated aircraft environment evaluation. These values were very close in value, as would be expected since they represent the same eyes only at different time periods. The values are also very similar to the average corneal thickness values reported by others as shown in Table 5.

CHAPTER VI

SUMMARY AND CONCLUSION

From the data obtained from the subjects in this study, the following conclusions were made:

1. When the Softperm contact lens was worn for two hours in a normal environment and baseline corneal thickness values were compared to the corneal thickness values obtained at the end of 120 minutes of lens wear, no significant changes in corneal thickness were observed ($p = 0.46$).

2. When the Softperm contact lens was worn for two hours in the simulated aircraft environment and baseline corneal thickness values were compared to the corneal thickness values obtained at the end of 120 minutes of lens wear, a statistically significant change (increase) in corneal thickness was observed ($p = 0.0027$).

3. When the corneal thickness measurements after 120 minutes of Softperm lens wear in the normal environment were compared to those after 120 minutes of wear in the

simulated aircraft environment, a statistically significant change (increase) in corneal thickness was observed ($p = 0.024$).

4. Corneal staining occurred or increased after 120 minutes of Softperm lens wear in greater than half the eyes in both environments. Staining changes occurred mostly in the central and superior cornea (Zones 1 & 2).

5. Bulbar conjunctival injection increased in approximately one-half of the eyes wearing the Softperm contact lens in the normal environment. In the simulated cockpit environment, all but one eye showed an increase in conjunctival injection.

6. No statistically significant difference was found when high or low LogMAR visual acuities taken at baseline were compared to the visual acuities found after 120 minutes of Softperm contact lens wear in the normal environment. The p values were $p = 0.61$ and $p = 0.25$ respectively.

7. No statistically significant difference was found when high and low LogMAR visual acuities taken at baseline were compared to the visual acuities found after 120

minutes of Softperm lens wear in the simulated aircraft environment. The p values were $p = 0.20$ and $p = .87$ respectively.

8. When the high and low LogMAR visual acuities found after 120 minutes of lens wear in the normal environment was compared to those found after 120 minutes of lens wear in the simulated aircraft environment, no statistically significant change was found for either the high or the low contrast chart. The p values were $p = 0.23$ and $p = 0.32$ respectively.

9. Residual astigmatism while wearing the Softperm contact lens was found for all but two eyes in this study. Flexure was calculated to average 57.6% of the corneal toricity for the eyes in this study.

10. Subjective comfort of the Softperm lens was not affected by wear in the simulated aircraft environment.

11. Nearly one half of the lenses moved less after two hours of wear than at baseline (15 minutes of wear). The incidence of lens tightening did not seem to increase in the simulated aircraft environment.

12. No increase in the amount of tear debris was noted after two hours of Softperm lens wear in either the normal or simulated aircraft environment.

13. There was only a slightly higher incidence of debris under the Softperm lens after two hours of wear in the simulated aircraft environment as compared to the normal environment.

14. No striae were observed in any eye during this study.

In conclusion, the only statistically significant finding of this study was an increase in corneal thickness after 120 minutes of Softperm lens wear in the simulated aircraft environment. This finding however, may be of little clinical significance since the amount of swelling that occurred is approximately equal to that which occurs with normal overnight eye closure.

The corneal staining that was noted in this study after two hours of Softperm contact lens wear in both environments is of clinical importance. This staining is believed to be a result of a tight fitting lens and therefore indicates the need for movement with this lens design. The author believes that if the lens does not move more than 0.25mm with blink in straight ahead gaze after 20 to 30 minutes of wear, the fit should be considered unsatisfactory and action taken to loosen the lens fit. If no movement can be obtained, another design should be considered.

The amount of bulbar conjunctival injection noted during this study is also a concern but the implication of this finding is unclear. As reported earlier, conjunctival injection has been a common finding of most studies where the eye has been exposed to decreased pO2 or O2 levels and decreased humidity. This seems to occur with and without contact lenses on the eye but is often worse worn a contact lens is present. Further evaluation as to the cause of this injection and the importance of it is needed.

It is this author's opinion that the Softperm contact lens can be safely worn in an aircraft environment similar to the one simulated by this study if the fit is deemed satisfactory and clinically significant corneal staining is not observed. In certain situations, this lens design has some benefits over other lens types presently approved for use by the USAF. The Softperm lens should be considered as an alternative if other lens designs are not performing satisfactorily.

A study similar to this one only longer in duration is advised to further evaluate this lens design in the simulated aircraft environment. Also, before approval for the Softperm lens design for use by aircrew members is granted, low atmospheric pressure testing to determine if there is any bubble formation beneath the lens and G force testing to see if the lens decenters should be accomplished.

APPENDIX A

SUBJECT HISTORIES

SUBJECT #1 JB

Date of Birth: 8/10/52 Age: 39

Male

Subject History: Negative history of eye trauma or significant eye desease. Positive history of mild dry eyes. Good physical health and is not on any medications. Intermitant soft contact lens wearer the past for 15 years. Subject wore PMMA lenses from 1966 to 1973. Average wearing time when lenses are worn is 1 to 8 hrs/day.

Refraction:	OD:	-2.50-0.50 X 137	V.A.: 20/15
	OS:	-3.25-0.25 X 025	V.A.: 20/15

Keratometry Readings:	OD:	45.37/46.50 @ 070
	OS:	45.50/46.62 @ 094

Slit lamp findings: Lids, lashes, and conjunctiva were all normal. Corneas were clear with no SPK or staining noted.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.40	-2.50	14.3
	OS:	7.40	-3.00	14.3

Fit: Alignment fit O.U.

Distance V.A. with lenses (Snellen):	OD: 20/15
	OS: 20/15

Over-refraction:	OD:	Plano	V.A.: 20/15
	OS:	Plano	V.A.: 20/15

SUBJECT #2 LB

Date of Birth: 6/27/68 Age: 22

Female

Subject History: Negative history of eye trauma or significant eye desease. Father is amblyopic with a history of eye muscle surgery. Good physical health reported Subject presently taking erythromycin, robatox, robatussin. Positive history of allergies. Subject has not worn contact lenses since November 1990.

Refraction:	OD:	-0.25-1.00 X 014	V.A.: 20/15
	OS:	PL -1.25 X 169	V.A. 20/15

Keratometry Readings	OD:	44.87/43.87 @ 084
	OS:	45.75/46.50 @ 092

Slit lamp findings: Lids, lashes, and conjunctiva were all normal. Corneas were clear with no SPK or staining noted.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.6	-0.50	14.3
	OS:	7.5	-0.25	14.3

Fit: OD: Slight apical clearance.
OS: Slight apical touch.

Distance V.A. with lenses (Snellen):	OD:	20/15
	OS:	20/15

Over-refraction:	OD:	+0.50-0.50 X 013	V.A.: 20/15
	OS:	+0.50-0.75 X 150	V.A.: 20/15

SUBJECT #3 EL

Date of Birth: 10/8/65 Age: 25

Male

Subject History: Strabismic surgical correction at age three and six. Slight exotropia. Negative history of ocular trauma or significant eye desease. Good physical health and is on no medications. Has worn daily wear soft toric contact lenses since age 17.

Refraction:	OD:	-2.50-1.00 X 006	V.A.: 20/15
	OS:	-2.00-1.50 X 106	V.A.: 20/15

Keratometry Readings:	OD:	44.50/45.50 @ 106
	OS:	44.25/45.62 @ 082

Slit lamp findings: Lids, lashes, and conjunctiva were all normal. No noted SPK or staining. Mild neovascularization superiorly O.U.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.7	-2.25	14.3
	OS:	7.6	-1.75	14.3

Fit: OD: Alignment fit.
OS: Alignment to slight touch.

Distance V.A. with lenses (Snellen).	OD:	20/20(+3)
	OS:	20/20(-1)

Over-refraction:	OD:	+0.50-0.50 X 162	V.A.: 20/15
	OS:	+1.50-0.50 X 010	V.A.: 20/15

SUBJECT # 4 BH

Date of Birth: 6/25/65 Age: 25

Male

Subject History: Negative history of eye trauma or significant eye desease. Good physical condition and is not on any medications. Soft contact lens wearer for 10 years. Has worn extended wear intermitantly for past 7 years, one week maximum at a time.

Refraction:	OD:	-5.00-1.00 X 013	V.A.: 20/15
	OS:	-4.00-0.75 X 161	V.A.: 20/15

Keratometry Readings:	OD:	43.87/45.12 @ 120
	OS:	43.50/44.25 @ 112

Slit lamp findings: Lids, lashes, and conjunctiva were all normal. Corneas were clear with slight staining superiorly OD. Mild neovascularization superiorly OU.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.7	-4.50	14.3
	OS:	7.7	-4.50	14.3

Fit: OD: Alignment fit.
OS: Slight apical clearence.

Distance V.A. with lenses (Snellen).	OD: 20/20(+2)
	OS: 20/15(-1)

Over-refraction:	OD:	+0.50-0.25 X 021	V.A.: 20/15
	OS:	+0.25-0.25 X 175	V.A.: 20/15

SUBJECT #5 KD

Date of Birth: 12/9/67 Age: 23

Female

Subject History: Negative history of eye trauma or significant eye desease. Grandparents had cataracts. Good physical health. Medications include benzamycine, fiorecet, allergy shots PRN, and ventylin inhalant PRN. Allergies: environmental, PCN, and thimerosal. Soft dailey wear contact lenses for 8 years followed by 2 1/2 years of RGP dailey wear.

Refraction:	OD:	-3.75-0.75 X 020	V.A.: 20/20
	OS:	-3.00-1.25 X 165	V.A.: 20/20

Keratometry readings:	OD:	41.75/43.75 @ 106
	OS:	41.25/43.62 @ 081

Slit lamp findings: Lids, lashes, and conjuntiva were all normal. Corneas were clear with no noted SPK or staining.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	8.0	-4.00	14.3
	OS:	7.9	-4.00	14.3

Fit: OD: Alignment to slight apical clearence.
OS: Alignment fit.

Distance V.A. with lenses (Snellen).	OD: 20/25
	OS: 20/15

Over-refraction:	OD:	+0.25-1.00 X 015	V.A.: 20/15
	OS:	+0.25-0.75 X 165	V.A.: 20/15

SUBJECT #6 JL

Date of Birth: 9/13/69 Age: 21

Male

Subject History: Negative history of ocular trauma, negative family ocular history. Good physical health. No medications at this time. Allergic to grasses, trees, and cats. No previous history of contact lens wear.

Refraction:	OD:	PL -1.00 X 116	V.A.: 20/15
	OS:	-0.25-0.75 X 062	V.A.: 20/15

Keratometry Readings:	OD:	45.50/46.50 @ 022
	OS:	45.75/45.86 @ 097

Slit lamp findings: Lids, lashes, and conjunctiva were normal. Corneas were clear with no noted staining or SPK. Tarsus had mild papilli O.U.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.4	-0.25	14.3
	OS:	7.4	-0.50	14.3

Fit:	OD:	Near alignment
	OS:	Near alignment

Distance V.A. with lenses (Snellen).	OD: 20/15
	OS: 20/15

Over-refraction:	OD:	+0.25-0.25 X 122	V.A.: 20/15
	OS:	PL -0.25 X 060	V.A.: 20/15

SUBJECT #7 BM

Date of Birth: 9/28/66 Age: 24

Female

Subject History: History of bilateral retinal detachments with decreased visual acuity resulting OD. No other significant ocular history. Reports good physical health and is not taking any medications. Soft contact lens wearer for 8.5 years including 4 years of extended wear, then switched to rigid gas permeable lenses 1.5 years ago. Presently wears lenses on average of 17 hours.

Refraction:	OD:	-6.75-0.50 X 021	V.A.: 20/40
	OS:	-5.50-0.75 X 171	V.A.: 20/15

Keratometry Readings:	OD:	43.25/43.75 @ 121
	OS:	43.25/44.00 @ 132

Slit lamp findings: Lids, lashes and conjunctiva were all normal. Corneas were clear with no SPK or other staining noted.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.6	-6.50	14.3
	OS:	7.6	-5.75	14.3

Fit: OD: Near alignment to slight apical clearence.
OS: Near alignment fit.

Distance V.A. with lenses (Snellen):	OD: 20/30 +3
	OS: 20/15 -3

Over-refraction:	OD:	plano-0.75 X 011	V.A.: 20/25
	OS:	+0.25-0.50 X 172	V.A.: 20/15

SUBJECT: #8 BM

Date of Birth: 3/22/61 Age: 30

Male

Subject History: Negative history of ocular trauma or significant eye desease. Good physical condition and presently not on any medications. Rigid gas permeable lens wearer for the past 6 years, soft lenses for 6 years prior to RGP wear. Average wearing time is 14 hours.

Refraction:	OD:	-2.75-0.50 X 018	V.A.: 20/15
	OS:	-2.75-0.50 X 170	V.A.: 20/15

Keratometry Readings:	OD:	44.37/45.37 @ 102
	OS:	43.87/45.37 @ 101

Slit lamp findings: Lids, lashes and conjunctiva were all normal. Cornea was clear with no significant SPK or other staining noted.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.60	-3.00	14.3
	OS:	7.60	-3.00	14.3

Fit: Near alignment OU.

Distacne V.A. with lenses. (Snellen):	OD:	20/15 -1
	OS:	20/15 -3

Over-refraction:	OD:	+0.25-0.25 X 108	V.A.: 20/15
	OS:	+0.25-0.50 X 044	V.A.: 20/15

SUBJECT #9 RR

Date of Birth: 7/19/62 Age: 28

Male

Subject History: Negative history of eye trauma or significant eye desease. Moderate neovascularization of the superior cornea OU. Wore daily wear soft lenses from 1984 to 1987 then changes to extended wear soft from 1987 to 1988. Advised to reduce extended wear to 2 days at a time in 1988 due to neo. Later told to wear lenses intermitantly only. Presently wearing daily wear soft for sports only. Maximum wearing time is 4 hours. Good physical condition and is not on any medication.

Refraction:	OD:	-2.50-0.75 X 164	V.A.: 20/15
	OS:	-2.00-0.75 X 172	V.A.: 20/15

Keratometry Readings:	OD:	43.00/44.12 @ 090
	OS:	43.12/44.25 @ 085

Slit lamp findings: Lids, lashes, and conjunctiva appear normal OU. OD cornea has mild neavascularization from 10 to 11 o'clock and 1 to 2 o'clock. OS cornea has mild to moderate neovascularization from 10 to 11 o'clock and 1 to 2 o'clock. Tarsus has trace papilli.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.80	-2.50	14.3
	OS:	7.80	-2.00	14.3

Fit: OD: On alignment to slight apical clearance.
OS: Slight apical clearance.

Distance V.A. with lenses (Snellen):	OD: 20/15 -2
	OS: 20/20

Over-refraction:	OD: +0.50-0.50 X 169	V.A.: 20/15
	OS: +0.50-0.50 X 010	V.A.: 20/15

SUBJECT #10   SS

Date of Birth: 6/7/68   Age: 22

Male

Subject History: Negative history of ocular trauma. Reports having severe conjunctivitis two times in past two years. Good physical health and not taking any medications. Subject is allergic to bee stings. Has worn soft E.W. lenses intermitantly for past 3 years. Usually wears them 1 week at a time when they are worn.

Refraction:	OD:	-2.00-1.00 X 177	V.A.: 20/15
	OS:	-1.50-1.50 X 003	V.A.: 20/15

Keratometry Readings:	OD:	43.47/45.00 @ 078
	OS:	43.62/45.12 @ 097

Slit lamp findings: Lids, lashes, and conjunctiva normal. Corneas were clear with no SPK or staining noted

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.70	-2.50	14.3
	OS:	7.70	-2.00	14.3

Fit: Slight apical clearance OU.

Distance V.A. with lenses (Snellen):	OD: 20/15
	OS: 20/15

Over-refraction:	OD:	+0.50-0.25 X 173	V.A.: 20/15
	OS:	+0.50-0.50 X 177	V.A.: 20/15

SUBJECT #11 HV

Date of Birth: 11/22/66 Age: 24

Male

Subject history: Negative history of eye trauma. Subject has had problems with GPC in the past. Good physical health. Not taking any medications at this time. Has worn contact lenses for a total of 10 to 11 years. Six years of daily wear soft lenses followed by 4 to 5 years of daily wear rigid gas premeable lenses.

Refraction:	OD:	-4.50-1.00 X 16(	V.A.: 20/15
	OS:	-3.25-0.75 X 002	V.A.: 20/20+2

Keratometry readings:	OD:	40.50/42.62 @ 080
	OS:	41.00/43.25 @ 106

Slit lamp findings: Lids, lashes, and bulbar conjunctiva were normal. Corneas were clear with no SPK or staining noted. Mild papilla on upper tarsus OU.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	8.00	-4.75	14.3
	OS:	8.00	-4.25	14.3

Fit: OD: Near alignment.
OS: Slight apical clearance.

Distance V.A. with lenses (Snellen):	OD:	20/15
	OS:	20/15

Over-refractiomn:	OD:	+0.50-0.50 X 025	V.A.: 20/15
	OS:	+0.25-0.50 X 172	V.A.: 20/15

SUBJECT #12 JB

Date of Birth: 10/17/66 Age: 24

Male

Subject History: Negative history of eye trauma or serious eye desease. Good physical health, no mendications being taken. No history of allergies. Intermitant soft daily wear for past one year. Subject wears soft toric contact lenses two or three times a month. No previous lens wear.

Refraction	OD:	-1.25-1.00 X 166	V.A.: 20/15
	OS:	-1.00-1.00 X 013	V.A.: 20/15

Keratometry readings:	OD:	44.25/45.75 @ 088
	OS:	44.37/45.50 @ 111

Slit lamp findings: Lids, lashes, and conjunctiva normal. Corneas were clear with no noted SPK or other staining. Tarsal plates were normal OU.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.50	-1.50	14.3
	OS:	7.50	-1.25	14.3

Fit: Near alignment to slight apical clearance OU>

Distance V.A. with lenses (Snellen):	OD:	20/20
	OS:	20/20

Over-refraction:	OD:	+0.25-0.73 X 180	V.A.: 20/15 -2
	OS:	+0.50-0.75 X 180	V.A.: 20/15 -1

SUBJECT #13 CS

Date of Birth: 3/25/66 Age: 25

Female

Subject history: Negative history of ocular trauma or significant eye desease. Subject does report mild dry eyes at times. Good physical health. Presently taking BCP's. No allergies reported. Subject wore PMMA hard lenses for 8 years, followed by rigid gas permeable lenses for 3 years. Has switched to toric soft lenses one and one-half months ago.

Refraction:	OD:	-2.25-1.50 X 019	V.A.: 20/15
	OS:	-2.25-1.00 X 149	V.A.: 20/15

Keratometry readings:	OD:	46.75/48.00 @ 112
	OS:	46.87/48.00 2 072

Slit lamp findings: Lids, lashes, and conjunctiva were normal OU. Corneas were clear with no significant SPK noted.

		Base Curve	Power	Diameter
Softperm lens parameters:	OD:	7.20	-2.75	14.3
	OS:	7.20	-2.25	14.3

Fit: OD: Slight apical clearance.
OS: Near alignment.

Distance V.A. with lenses. (Snellen):	OD: 20/15
	OS: 20/15

Over-refraction:	OD:	+0.50-0.75 X 010	V.A.: 20/15
	OS:	+0.50-0.75 X 168	V.A.: 20/15

APPENDIX B

SOFTPERM CONTACT LENS INFORMATION

SoftPerm™
(synergicon A)

Contact Lens
Rigid Center/Soft Hydrophilic Skirt
U.S. Pat. 3,876,581 4,093,361 4,121,885

PACKAGE INSERT: IMPORTANT – Please read carefully and keep this information for future use.

SPHERICAL LENSES FOR:

Cosmetic Refractive Ametropia (not aphakic) may include astigmatism not in excess of 4.00 diopters which does not interfere with visual acuity.

DESCRIPTION:

The SoftPerm™ (synergicon A) Contact Lens is available as a spherical lens only. The SoftPerm™ Contact Lens is a rigid circular shell with a soft hydrophilic skirt, generally spherical surfaces, and the following dimensions:

Chord Diameter: 14.3 Millimeters

Center Thickness: 0.08 to 0.28 millimeters

Base Curve: 8.10 to 7.10 millimeters (0.10 millimeter increments)

Power: +6.00 D to −10.00 D (0.25 D increments)
−10.50 D to −13.00 D (in 0.50 D increments)

The lens material, (pentasilcon P), which comprises the optical phase of the lens, is a rigid, oxygen-permeable copolymer: Poly (tertiarybutylstyrene-co-methyl-methacrylate-co-maleic anhydride-co-penta methyl disiloxanyl-methacrylate-co-1,1,1-trimethylolpropane trimethacrylate).

The lens material, which comprises the soft phase of the lens is a hydrophilic copolymer: 2-hydroxyethyl-methacrylate-co-2-methoxyethyl methacrylate-co-1,1,1-trimethylolpropane trimethacrylate.

The composite material is synergicon A.

The physical properties of the rigid optical phase of the lens are:

Specific Gravity: 1.015 at 25°C.

Refractive Index: 1.53 (N_o/25°C).

Light Transmittance: 88–92% (in the visible range).

Surface Character: Wettable (Contact Angle is 21° [CLMA Method]).

Water Content: $<$[illegible] by Weight.

Oxygen Permeabi[illegible] 14 $\times$ 10[illegible] (cm^2/sec) (ml O_2/ml-mm Hg) (as measured with Schema Versatae Oxygen Flux Meter).

The physical properties of the soft hydrophilic phase of the lens are:

Water Content: 25%

Surface Character: Hydrophilic

Oxygen Permeability: 5.5 $\times$ 10^{-11} (cm^2/sec) (ml O_2/ml-mm Hg) (as measured with Schema Versatae Oxygen Flux Meter).

ACTIONS:

The SoftPerm™ Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS (uses)

The SoftPerm™ Contact Lenses are indicated for daily wear for the correction of Cosmetic Refractive Ametropia (not aphakic) by persons with non-diseased eyes requiring a spherical correction of +6.00 to −13.00 diopters and may exhibit astigmatism not in excess of 4.00 diopters which does not interfere with visual acuity.

* Package Insert, Softperm Contact Lens

Step-by Step Procedure for Trial Fitting the Softperm Contact lens*

1. Take Keratometer readings and convert "flat K" to mm.

2. Select the base curve of the diagnostic lens as a function of corneal toricity as follows:

Corneal Toricity(D)	Base Curve(mm)
1.37D or less	Flat K to 0.1 mm steeper than flat K
1.50D to 2.75D	0.1 mm to 0.2 mm steeper than flat K
Over 2.75D	0.2 mm to 0.3 mm steeper than flat K

If deviations from the above base curve selection table are considered, it is best to err slightly on the steep side. Thus, the final base curve should be within the recommended range or perhaps 0.1 mm steeper.

3. Performance evaluation
   Allow a minimum of 10-15 minutes equilibration on the eye before evaluating the trial lens. Allow 20-30 minutes if there is initial edge standoff.

   If small bubbles are trapped under the lens on insertion, they should be massaged out or allowed to dissipate before evaluation.

   If dry spots are observed, clean and reinsert the lens before proceeding.

4. Criteria for ideal fit (after adequate equilibration)

   Good comfort and good centration without limbal impingement

   At least 0.25 mm of free movement on upgaze blink
   -Direct patient to look up and observe lower lens margin
   -Have patient blink in upgaze
   -Free movement means the lens margin slides without dragging conjunctiva or superficial vessels

   Good tear exchange as indicated by a rapid outflow of fluorescein and the absence of trapped tears

* Professional Fitting Guide, Sola/Barnes-Hind

APPENDIX C

TABLES

TABLE 1

Advantages of Contact Lenses

1. Universally compatable with life support sustems such as oxygen masks and personal protective devices such as helmets and gas masks.
2. No interference with the use of optical instruments, such as helmet mounted target sights and night vision goggles.
3. Provide an increase in the size of the field of vision since there is no frame to limit or obsruct the field of view.
4. No frame discomfort under helmets and headstes.
5. No lens fogging from sudden temperature changes.
6. Continue to provide good vision inincliment weather since they do not mist.
7. Perspiration problems are eliminated. No sweat on lenses that can interfere with vision. No frames to slip or fall off.
8. Eliminate the problem of reflections that can occur with spectacles.
9. Provide more natural vision since they sit on the eye, not in front of it. Radial and oblique astigmatism that can occur when looking through the periphery of spectacle lenses is eliminated.
10. Provide improved visual acuity or visual performance in certain medical/optical conditions, such as keratoconus, aphakia, anisometropia, or irregular corneal topography.

TABLE 2

Disadvantages of Contact Lenses

1. Not tolerated by all individuals. Adjustment period required before full-time wear can be achieved, especially with rigid lenses. Full-time wear not always possible due to lens discomfort.
2. May not fully correct refractive error (residual astigmatism) or may not provide visual acuity that is as sharp as with spectacles. Vision may flucuate periodically. May not provide glare protection. Do not give a reading prescription for the presbyopic aviator.
3. Lenses may become displaced or dislodge under Gz forces or for various other reasons.
4. Foreign bodies may get trapped beneath the lens compromising both vision and safety.
5. Cornea may be more prone to edema and other changes due to hypoxia caused by wearing the lenses at high altitudes.
6. Require much more care to properly maintain than spectacles which may be difficult in certain situations.
7. More expensive, more time consuming to fit, and more difficult to fit than spectacles. They require professional eye care for proper fitting and follow-up and therefore are an added burden to the medical care system. This creates logistical, economical, and administrative problems.
8. May cause corneal changes that can create spectacle blur problems, more commom with rigid lenses.
9. In a chemical warefare environment, lenses first act as a barrier, then may absorb the chemical, prolonging chemical exposure.
10. Provide less protection from blunt trauma and flying debris.

TABLE 3

Advantages and Disadvantages of Spectacles

Advantages of spectacles

1. Tolerated by nearly all who wear them.
2. Will fully correct all non-pathological refractive errors.
3. Wearing time is unlimited
4. May provide better impact and wind protection.
5. Provide excellent, stable visual acuity.
6. Can be tinted to provide sun and glare protection.
7. Available with bifocal correction.
8. Well proven in flight.
9. Easily and quickly put on and removed.

Disadvantages of Spectalces

1. Integration with some optical ysystems and equipment often difficult.
2. Must be specifically designed to be compatable with life support and protective gear.
3. May mist or fog in certain environments.
4. Restrict corrected field of view. Frame can obscure field of view.
5. Can displace or oscillate during acceleration (Gz) or severe vibration and reduce visual acuity.
6. Perspiration may get on lenses or cause frames to slip.
7. May become uncomfortable under helmets and/or headsets.
8. Distortions and annoying or distracting reflections can occur.
9. Hazard of shattered lenses exists.

TABLE 4

Relationship Of Altitude, Atmospheric Pressure & Partial Pressure Of Oxygen (pO2)

Altitude (ft.)	Atmos. Pressure (mmHg)	pO2 (mmHg)
Sea Level	760	155
10,000	522	110
20,000	350	73
30,000	226	47
40,000	141	30
50,000	87	18

TABLE 5

Historical Review of Corneal Thickness Values

Investigator	Year	Corneal Thickness (mm.)	No. of eyes
Blix	1880	0.482-.576	10
Von Bahr	1948	0.565+/-0.035	224
Maurice & Giardini	1951	0.507+/-0.040	14
Lauergue & Kelecom	1962	0.510+/-0.040	198
Donaldson	1966	0.522+/-0.041	268
Martola & Baum	1968	0.523+/-0.039	209
Mishma & Hedbys	1968	0.518+/-0.020	40
Mandell & Polse	1969	0.506+/-0.040	32
Hansen	1971	OD:0.520+/-0.018 OS:0.524+/-0.020	76 74
Binder*	1977	0.490+/-0.015	32
Binder**	1977	0.607	32
Barr	1979	0.5308+/-0.028	48
Holden	1983	0.5029+/-0.023	10

* Haag-Streit Pachometer
** Electronic Digital Pachometer

TABLE 6

Conversion Of The LogMAR And 6-m Snellen Notations
To 20-ft Snellen And Decimal Notations

LogMAR	Snellen (6 m)	Snellen (20 ft)	Decimal
1.0	6/60	20/200	0.10
0.9	6/48	20/160	0.125
0.8	6/38	20/125	0.16
0.7	6/30	20/100	0.20
0.6	6/24	20/80	0.25
0.5	6/19	20/63	0.32
0.4	6/15	20/50	0.40
0.3	6/12	20/40	0.50
0.2	6/9.5	20/32	0.63
0.1	6/7.5	20/25	0.80
0.0	6/6	20/20	1.00
-0.1	6/4.8	20/16	1.25
-0.2	6/3.8	20/12.5	1.60
-0.3	6/3	20/10	2.00

TABLE 7

Humidity Level Entering and Exiting the Goggles for Each Subject and Average Humidity Levels

Subject	In	Out
1	2	14
2	2	11
3	2	15
4	2	14
5	2	12
6	3	15
7	2	22
8	2	18
9	-	-
10	3	11
11	2	10
Avg.	2.2%	14.2%

TABLE 8

Tear Film Debris Scale

0 - None - No debris noted in the tear film.

1 - Mild - presence of minimal, small, individual particles.

2.- Moderate - presence of moderate, small, individual particles.

3 - Severe - presence of severe, coalesced, particles.

TABLE 9

Lens Debris Scale

0 - No debris present beneath lens

1 - Presence of small (<0.1mm), individual particles of debris.

2 - Coalcesing areas of debris across one-third or less of the area beneath the lens.

3 - Coalescing areas of debris across one-third tc two-thirds of the area beneath the lens.

4 - Debris present beneath more than two-thirds of the area beneath the lens.

TABLE 10

Corneal Staining Grading Scale

0 - None - No epithelial staining.

1 - Mild - Regional occasional superficial staining (stippling).

2 - Moderate - Regional dense (1mm or greater) diffuse punctate staining.

3 - Severe - Epithelial loss (e.g. abrasions).

TABLE 11

Bulbar Conjunctiva Grading Scale

0 - None - Normal appearing conjunctiva.

1 - Mild - Superficial regional injection.

2 - Moderate - Superficial diffuse injection.

3 - Severe - Superficial, deep diffused injection.

TABLE 12

Comparison of Refractive Cylinder, Measured Corneal Toricity, Calculated Residual Astigmatism, and Actual Residual Astigmatism

Subject & Eye	Refractive Cylinder	Corneal Toricity	C.R.A.	Measured Resid. Astig.
1/OD	-0.50X137	-1.12X160	-0.62X070	Plano
1/OS	-0.25X025	-1.12X004	-0.87X094	Plano
2/OD	-1.00X014	-1.00X174	Plano	-0.50X013
2/OS	-1.25X169	-0.75X002	-0.50X169	-0.75X150
3/OD	-1.00X006	-1.00X016	Plano	-0.25X162
3/OS	-1.50X003	-1.37X172	-0.12X003	-0.50X010
4/OD	-1.00X013	-1.25X030	-0.25X120	-0.25X021
4/OS	-0.75X161	-0.75X022	Plano	-0.25X175
5/OD	-0.75X020	-2.00X016	-1.25X106	-1.00X015
5/OS	-1.25X165	-2.37X171	-1.12X081	-0.75X165
6/OD	-1.00X116	-1.00X112	Plano	-0.25X122
6/OS	-0.75X062	-0.12X007	-0.62X062	-0.25X060
7/OD	-0.50X021	-0.75X030	-0.25X120	-0.75X011
7/OS	-0.75X171	-0.75X042	Plano	-0.50X172
8/OD	-0.75X018	-1.00X012	-0.25X102	-0.25X108
8/OS	-0.50X170	-1.50X011	-1.00X101	-0.50X044
9/OD	-0.75X164	-1.12X180	-0.37X090	-0.50X169
9/OS	-0.75X172	-1.12X175	-0.37X085	-0.75X010
10/OD	-1.00X177	-1.25X168	-0.25X078	-0.25X173
10/OS	-1.50X003	-1.50X007	Plano	-0.50X177
11/OD	-1.00X168	-2.12X170	-1.12X080	-0.50X025
11/OS	-0.75X173	-2.25X016	-1.50X106	-0.50X172
12/OD	-1.00X166	-1.50X002	-0.50X088	-0.75X180
12/OS	-1.00X013	-1.12X021	-0.12X111	-0.75X180
13/OD	-1.50X019	-1.25X022	-0.25X019	-0.75X010
13/OS	-1.00X149	-1.12X162	-0.12X072	-0.75X168

TABLE 13

Center Thickness, Flexure, and Flexure as a % of Corneal Toricity

Subject/Eye	Center Thickness	Flexure	Flexure as a % of Corneal Toricity
1/OD	0.122	-0.62x160	55%
1/OS	0.122	-0.87x004	78%
2/OD	0.138	-0.50x013	50%
2/OS	0.172	-0.25x150	33%
3/OD	0.120	-0.25x162	25%
3/OS	0.148	-0.37x010	27%
4/OD	0.092	-0.50x021	40%
4/OS	0.082	-0.25x175	33%
5/OD	0.072	-2.25x015	100%
5/OS	0.108	-1.87x153	79%
6/OD	0.169	-0.25x122	25%
6/OS	0.158	-0.37x152	*
7/OD	0.080	-1.00x011	100%
7/OS	0.082	-0.50x172	66%
8/OD	0.102	Plano	0%
8/OS	0.110	-0.50x011	33%
9/OD	0.110	-0.87x169	78%
9/OS	0.128	-1.12x010	100%
10/OD	0.111	-0.50x173	40%
10/OS	0.119	-0.50x177	33%
11/OD	0.085	-1.62x025	76%
11/OS	0.090	-2.00x172	89%
12/OD	0.141	-1.25x180	83%
12/OS	0.145	-0.87x180	78%
13/OD	0.120	-0.50x010	40%
13/OS	0.128	-0.87x168	78%

* ATR Flexure

TABLE 14

Eyes Randomly Selected For Statistical Analysis

Subject	Eye
1	OS
2	OD
3	OS
4	OS
5	OS
6	OS
7	OD
8	OS
9	OD
10	OD
11	OD
12*	OS
13*	OD

*These eyes used for the statistical analysis in the normal environment only.

Table 15

Corneal Thickness Changes/Normal Environment

Subject/Eye	Measurement(mm.) Baseline	120 min.	Difference (mm.)	% Change
1/OD	0.5526	0.5393	-0.0133	-2.4%
1/OS	0.5224	0.5256	0.0032	+0.6%
2/OD	0.4909	0.4810	-0.0099	-2.0%
2/OS	0.4809	0.5259	0.0450	+9.4%
3/OD	0.5160	0.5077	-0.0083	-1.6%
3/OS	0.5118	0.5104	-0.0014	-0.3%
4/OD	0.5276	0.5312	0.0036	+0.7%
4/OS	0.5317	0.5218	-0.0099	-1.9%
5/OD	0.5320	0.5373	0.0053	+1.0%
5/OS	0.5108	0.4949	-0.0159	-3.0%
6/OD	0.5167	0.5410	0.0243	+4.7%
6/OS	0.5200	0.5482	0.0282	+5.4%
7/OD	0.5072	0.5016	-0.0056	-1.1%
7/OS	0.5318	0.5228	-0.0090	-1.7%
8/OD	0.5129	0.4976	-0.0153	-3.8%
8/OS	0.4914	0.5126	0.0212	+4.3%
9/OD	0.5706	0.5796	0.0090	+1.6%
9/OS	0.5573	0.5540	-0.0033	-0.6%
10/OD	0.4656	0.4550	-0.0106	-2.3%
10/OS	0.4393	0.4603	0.0210	+4.8%
11/OD	0.5656	0.5684	0.0028	+0.5%
11/OS	0.5499	0.5461	-0.0038	-0.7%
12/OD	0.5617	0.5511	-0.0106	-1.9%
12/OS	0.5412	0.5658	0.0246	+4.5%
13/OD	0.4690	0.4728	0.0038	+0.8%
13/OS	0.4781	0.4864	0.0083	+1.7%

TABLE 16

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in Corneal Thickness Measurements Between Baseline and 120 Minutes in the Normal Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
13	0.00304	0.01425	0.00395	0.77	0.46

TABLE 17

Corneal Thickness Changes/Simulated Aircraft Environment

Subject/Eye	Measurement(mm.) Baseline	120 min.	Difference (mm.)	% Change
1/OD	0.5340	0.5369	0.0029	+0.5%
1/OS	0.5352	0.5497	0.0145	+2.7%
2/OD	0.4856	0.5362	0.0506	+10.4%
2/OS	0.4913	0.5471	0.0558	+11.4%
3/OD	0.5236	0.5103	-0.0133	-2.5%
3/OS	0.4871	0.5054	0.0183	+3.8%
4/OD	0.5580	0.5724	0.0144	+2.6%
4/OS	0.5315	0.5580	0.0265	+5.0%
5/OD	0.5165	0.5154	-0.0011	-0.2%
5/OS	0.5010	0.5107	0.0097	+1.9%
6/OD	0.5289	0.5602	0.0313	+5.9%
6/OS	0.5355	0.5648	0.0293	+5.5%
7/OD	0.5310	0.5735	0.0425	+8.0%
7/OS	0.5016	0.5468	0.0452	+9.0%
8/OD	0.4986	0.5248	0.0262	+5.3%
8/OS	0.4874	0.5049	0.0175	+3.6%
9/OD	0.5602	0.5494	-0.0108	-1.9%
9/OS	0.5638	0.5662	0.0024	+0.4%
10/OD	0.4248	0.4474	0.0251	+5.9%
10/OS	0.4207	0.4474	0.0267	+6.3%
11/OD	0.5467	0.5500	0.0033	+0.6%
11/OS	0.5367	0.5449	0.0082	+1.5%

TABLE 18

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in Corneal Thickness Measurements Between Baseline and 120 Minutes in the Simulated Aircraft Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
11	0.02059	0.01722	0.00519	3.97	0.0027

TABLE 19

Summary Statistics and t Statistic, of a Two-Tailed Paired t-test for the Difference in Corneal Thickness Measurements Between 120 Mins. in the Normal Environment and 120 Mins. in the Simulated Aircraft Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
11	0.01958	0.02436	0.00734	2.67	0.024

TABLE 20

Corneal Staining: Normal Environment
(Baseline/120 min.)

Subject/Eye	Zone 1	2	3	4	5
1/OD	0/0	0/1	0/1	0/1	0/0
1/OS	1/0	1/1	0/0	0/1	0/0
2/OD	0/2	0/1	0/1	0/1	0/1
2/OS	0/3	0/1	0/1	0/1	0/1
3/OD	0/2	0/0	0/0	0/0	0/0
3/OS	0/2	0/1	0/1	0/1	0/1
4/OD	0/1	1/0	0/0	0/0	1/1
4/OS	0/0	0/0	0/0	0/0	0/0
5/OD	0/0	0/1	0/0	0/0	0/0
5/OS	0/1	0/1	0/0	0/0	0/0
6/OD	0/0	0/0	0/0	0/0	0/0
6/OS	0/0	0/0	0/0	0/0	0/0
7/OD	0/1	0/1	0/1	0/2	0/2
7/OS	0/1	0/1	0/1	0/1	0/1
8/OD	0/1	0/1	0/0	0/1	1/0
8/OS	1/2	0/1	0/1	0/1	1/1
9/OD	1/2	0/1	0/1	0/1	0/1
9/OS	0/1	0/1	0/1	0/1	0/0
10/OD	0/0	0/1	0/0	0/0	0/0
10/OS	0/2	0/1	0/1	0/1	0/1
11/OD	0/0	0/1	0/0	0/1	0/0
11/OS	0/2	0/1	0/1	0/1	0/1
12/OD	0/1	0/2	0/0	0/0	0/1
12/OS	0/1	0/1	0/0	0/0	0/0
13/OD	0/2	0/1	0/0	0/0	0/0
13/OS	0/1	0/0	0/0	0/0	0/0

TABLE 21

Corneal Staining: Aircraft Environment
(Baseline/120 min.)

Subject/Eye	Zone 1	2	3	4	5
1/OD	0/1	0/1	0/0	0/0	0/0
1/OS	0/2	0/1	0/0	0/1	0/0
2/OD	0/2	0/1	0/1	0/1	0/1
2/OS	0/3	0/0	0/1	0/1	0/1
3/OD	0/2	0/0	0/0	1/1	0/0
3/OS	1/2	0/0	1/1	1/1	0/1
4/OD	0/0	0/0	0/0	0/1	0/0
4/OS	1/0	1/1	0/0	1/1	0/0
5/OD	0/2	0/1	0/0	0/0	0/0
5/OS	0/2	0/1	0/0	0/0	0/0
6/OD	0/0	0/0	0/0	0/0	0/0
6/OS	0/0	0/0	0/0	0/0	0/0
7/OD	2/2	1/1	1/1	1/1	1/1
7/OS	0/0	0/0	0/0	0/1	0/1
8/OD	0/1	0/0	0/0	0/1	0/0
8/OS	0/2	0/1	0/1	1/1	0/1
9/OD	0/1	0/1	0/0	0/0	0/0
9/OS	0/1	0/0	0/0	0/0	0/0
10/OD	0/0	0/0	0/1	0/0	0/0
10/OS	0/0	0/0	0/0	0/0	0/0
11/OD	0/2	0/2	1/1	0/1	0/1
11/OS	1/1	1/1	1/1	0/1	0/1

TABLE 22

Conjunctival Injection/Normal Environment

Subject/Eye	Grade Baseline	Grade 120 min.
1/OD	0	0
1/OS	0	1
2/OD	0	1
2/OS	0	1
3/OD	0	1
3/OS	0	1
4/OD	1	1
4/OS	1	1
5/OD	0	1
5/OS	0	1
6/OD	0	0
6/OS	0	1
7/OD	1	1
7/OS	1	1
8/OD	0	0
8/OS	C	0
9/OD	0	0
9/OS	0	1
10/OD	0	1
10/OS	0	1
11/OD	1	1
11/OS	1	1
12/OD	1	1
12/OD	1	1
13/OD	0	1
13/OS	0	1

TABLE 23

Conjunctival Injection/Aircraft Environment

Subject/Eye	Grade Baseline	Grade 120 min.
1/OD	0	1
1/OS	0	1
2/OD	0	1
2/OS	0	1
3/OD	1	2
3/OS	1	2
4/OD	1	1
4/OS	1	2
5/OD	1	2
5/OS	1	2
6/OD	0	1
6/OS	0	1
7/OD	0	1
7/OS	0	1
8/OD	0	1
8/OS	0	1
9/OD	0	2
9/OS	0	2
10/OD	1	2
10/OS	1	2
11/OD	1	2
11/OS	1	2

TABLE 24

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in High Contrast LogMAR Visual Acuity Between Baseline and 120 Minutes in the Normal Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
13	-0.0123	0.0839	0.0233	-0.53	0.61

TABLE 25

LogMAR Visual Acuity/Normal Environment
High Contrast

Subject/Eye	Baseline	120 min.	log-unit change
1/OD	-0.10	-0.04	+0.06
1/OS	-0.02	0.00	+0.02
2/OD	+0.02	+0.04	+0.02
2/OS	-0.02	+0.04	+0.06
3/OD	+0.02	0.00	-0.02
3/OS	+0.10	+0.10	0.00
4/OD	-0.02	-0.04	-0.02
4/OS	-0.02	-0.04	-0.02
5/OD	+0.18	+0.10	-0.08
5/OS	0.00	0.00	0.00
6/OD	-0.02	0.00	+0.02
6/OS	-0.08	-0.10	-0.02
7/OD	+0.32	+0.32	0.00
7/OS	+0.06	-0.02	-0.08
8/OD	-0.02	-0.02	0.00
8/OS	0.00	+0.18	+0.18
9/OD	0.00	-0.12	-0.12
9/OS	-0.02	-0.12	-0.10
10/OD	-0.02	-0.04	-0.02
10/OS	-0.10	-0.08	+0.02
11/OD	-0.04	-0.12	-0.18
11/OS	+0.08	-0.04	-0.12
12/OD	-0.02	-0.06	-0.04
12/OS	-0.06	-0.02	+0.04
13/OD	0.00	-0.06	-0.06
13/OS	-0.02	-0.04	-0.02

TABLE 26

LogMAR Visual Acuity/Normal Environment
Low Contrast

Subject/Eye	Baseline	120 min.	log-unit change
1/OD	+0.06	+0.02	-0.04
1/OS	+0.16	+0.18	+0.02
2/OD	+0.18	+0.20	+0.02
2/OS	+0.22	+0.22	0.00
3/OD	+0.22	+0.18	-0.04
3/OS	+0.20	+0.18	-0.02
4/OD	+0.06	+0.06	0.00
4/OS	+0.06	+0.06	0.00
5/OD	+0.30	+0.32	+0.02
5/OS	+0.16	+0.16	0.00
6/OD	+0.22	+0.18	-0.04
6/OS	+0.08	0.00	-0.08
7/OD	+0.50	+0.38	-0.12
7/OS	+0.20	+0.24	+0.04
8/OD	+0.22	+0.20	-0.02
8/OS	+0.30	+0.36	+0.06
9/OD	+0.12	+0.02	-0.10
9/OS	+0.30	+0.12	-0.28
10/OD	+0.12	+0.16	+0.04
10/OS	+0.10	+0.18	+0.08
11/OD	+0.06	0.00	-0.06
11/OS	+0.20	+0.16	-0.04
12/OD	+0.18	+0.08	-0.10
12/OS	+0.16	+0.18	+0.02
13/OD	+0.24	+0.22	-0.02
13/OS	+0.16	+0.22	+0.06

TABLE 27

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in Low Contrast *LogMAR* Visual Acuity Between Baseline and 120 Minutes in the Normal Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
13	-0.0185	0.0557	0.0154	-1.20	0.25

TABLE 28

LogMAR Visual Acuity/Aircraft Environment
High Contrast

Subject/Eye	Baseline	120 min.	log-unit change
1/OD	-0.12	-0.08	+0.04
1/OS	+0.04	+0.10	+0.06
2/OD	+0.04	+0.02	-0.02
2/OS	+0.02	+0.10	+0.08
3/OD	0.00	0.00	0.00
3/OS	+0.02	+0.08	+0.06
4/OD	0.00	-0.10	-0.10
4/OS	-0.10	-0.10	0.00
5/OD	+0.10	+0.12	+0.02
5/OS	-0.06	-0.14	-0.08
6/OD	-0.10	-0.10	0.00
6/OS	-0.20	-0.12	+0.08
7/OD	+0.32	+0.32	0.00
7/OS	+0.06	-0.02	-0.08
8/OD	+0.04	0.00	-0.04
8/OS	-0.02	+0.10	+0.12
9/OD	-0.02	-0.04	-0.02
9/OS	-0.02	-0.02	0.00
10/OD	-0.10	-0.12	-0.02
10/OS	-0.10	-0.10	0.00
11/OD	-0.12	-0.02	+0.10
11/OS	+0.10	0.00	-0.10

TABLE 29

Summary Statistics and t Statistic, of a Two-Tailed Paired t-test for the Difference ir High Contrast LogMAR Visual Acuity Between Baseline and 120 Minutes in the Simulated Aircraft Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
11	0.0255	0.0620	0.0187	1.36	0.20

TABLE 30

LogMAR Visual Acuity/Aircraft Environment
Low Contrast

Subject/Eye	Baseline	120 min.	log-unit change
1/OD	0.00	+0.02	+0.02
1/OS	+0.22	+0.28	+0.06
2/OD	+0.20	+0.18	-0.02
2/OS	+0.20	+0.26	+0.06
3/OD	+0.20	+0.20	0.00
3/OS	+0.20	+0.22	+0.02
4/OD	+0.20	+0.12	-0.08
4/OS	+0.08	+0.04	-0.04
5/OD	+0.24	+0.18	-0.06
5/OS	+0.04	+0.04	0.00
6/OD	+0.02	+0.08	+0.06
6/OS	-0.02	+0.02	+0.04
7/OD	+0.50	+0.40	-0.10
7/OS	+0.20	+0.24	+0.04
8/OD	+0.20	+0.20	0.00
8/OS	+0.30	+0.32	+0.02
9/OD	+0.10	0.00	-0.10
9/OS	+0.20	+0.20	0.00
10/OD	-0.02	-0.02	0.00
10/OS	+0.06	+0.08	+0.02
11/OD	+0.04	+0.20	+0.16
11/OS	+0.22	+0.18	-0.04

TABLE 31

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in Low Contrast LogMAR Visual Acuity Between Baseline and 120 Minutes in the Simulated Aircraft Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
11	0.0036	0.0731	0.0220	0.16	0.87

TABLE 32

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in High Contrast LogMAR Visual Acuity Between 120 Mins. in the Normal Environment and 120 Mins. in the Simulated Aircraft Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
11	0.0382	0.0998	0.0301	1.27	0.23

TABLE 33

Summary Statistics and t Statistic, of a Two-Tailed Paired t-Test for the Difference in Low Contrast LogMAR Visual Acuity Between 120 Mins. in the Normal Environment and 120 Mins. in the Simulated Aircraft Environment

Test of MU = 0.00 vs MU N.E. 0.00

N	Mean	STDEV	SE Mean	t	P Value
11	0.0255	0.0810	0.0244	1.04	0.32

TABLE 34

Distance Visual Acuity with Lenses, Over-refraction, and Resulting Visual Acuity

Subject/Eye	Distance V.A. with Lenses (Snellen)	Over-refraction	V.A.
1/OD	20/15	Plano	20/15
1/OS	20/15	Plano	20/15
2/OD	20/15	+0.50-0.50 x 013	20/15
2/OS	20/15	+0.50-0.75 x 150	20/15
3/OD	20/20(+3)	+0.50-0.50 x 162	20/15
3/OS	20/20(-1)	+1.50-0.50 x 010	20/15
4/OD	20/20(+2)	+0.50-0.25 x 021	20/15
4/OS	20/15(-1)	+0.25-0.25 x 175	20/15
5/OD	20/25	+0.25-1.00 x 015	20/15
5/OS	20/15	+0.25-0.75 x 165	20/15
6/OD	20/15	+0.25-0.25 x 122	20/15
6/OS	20/15	Pl -0.25 x 060	20/15
7/OD	20/30(+3)	Pl -0.75 x 011	20/25
7/OS	20/15(-3)	+0.25-0.50 x 172	20/15
8/OD	20/15(-1)	+0.25-0.25 x 108	20/15
8/OS	20/15(-3)	+0.25-0.50 x 044	20/15
9/OD	20/15(-2)	+0.50-0.50 x 169	20/15
9/OS	20/20	+0.50-0.50 x 010	20/15
10/OD	20/15	+0.50-0.25 x 173	20/15
10/OS	20/15	+0.50-0.50 x 177	20/15
11/OD	20/15	+0.50-0.50 x 025	20/15
11/OS	20/15	+0.25-0.50 x 172	20/15
12/OD	20/20	+0.25-0.73 x 180	20/15(-2)
12/OS	20/20	+0.50-0.75 x 180	20/15(-1)
13/OD	20/15	+0.50-0.75 x 010	20/15
13/OS	20/15	+0.50-0.75 x 168	20/15

TABLE 35

Results Of Questionnaire #1, Subjective Comfort & Vision After 2 Hrs. In The Normal Environment.

Subject	Comfort Grade	Subjective Vision
1	1	SATISFACTORY
2	1	SATISFACTORY/STABLE
3	OD:2,OS:3	SATISFACTORY
4	0	VERY SATISFACTORY
5	2	SATISFACTORY BUT VARIABLE
6	2	VARIABLE
7	0	VERY CLEAR
8	1	SATISFACTORY BUT VARIABLE
9	2	SATISFACTORY
10	1	SATISFACTORY/STABLE
11*	N/A	N/A
12	2	SATISFACTORY/STABLE
13	1	SATISFACTORY/ BETTER THAN SOFT TORIC, NOT AS GOOD AS RGP

SCALE:
0 - No sensation or lens awareness/excellent comfort
1 - Occasional slight awareness
2 - Consistent awareness/slight discomfort
3 - Consistent discomfort
4 - Pain/very poor comfort

*Did not respond to the questionnaire.

TABLE 36

Results Of Questionnaire #2, Subjective Comfort During Two Hours Exposure To The Simulated Aircraft Environment

Subject	Initial	30 min.	60 min.	90 min.	120 min.
1	1	0	1	1	1
2	1	1	1	1	2
3	2	0	0	0	1
4	1	1	1	2	1
5	1	1	OD:1/OS:2	2	OD:2/OS:3
6	2	1	1	1	1
7	1	2	1	1	1
8	1	1	1	2	2
9	1	2	2	2	2
10	1	1	1	2	2
11	1	1	2	2	2

Scale:
0 - No sensation or lens awareness/excellent comfort
1 - Occasional slight awareness
2 - Consistent awareness/slight discomfort
3 - Consistent discomfort
4 - Pain/very poor comfort

TABLE 37

Subjective Vision Changes During Two Hours Exposure To Simulated Aircraft Environment

Subject	Response
1	No Change
2	No Change
3	No Change
4	No Change
5	Yes:Blurs Occasionally
6	No Change
7	No Change
8	Yes:Slight Decrease, Very Minimal Fogginess
9	No Change
10	No Change
11	Yes:Vision Decreased, Intermittant

TABLE 38

Lens Movement Changes After 120 Minutes of Wear

Subject	Normal Environment	Simulated Aircraft Environment
1	N/C	N/C
2	Tightened	Tightened
3	Tightened	Tightened
4	N/C	Loosened
5	N/C	Tightened
6	Tightened OD N/C OS	Tightened
7	Tightened	N/C
8	Loosened OD N/C OS	Loosened OD Tightened OS
9	Tightened	N/C
10	N/C OD Tightened OS	N/C
11	N/C OD Tightened OS	Tightened OD N/C OS
12	N/C	
13	Tightened	

TABLE 39

Tear Film Debris/Normal Environment

Subject/Eye	Grade Baseline	120 min.
1/OD	2	1
1/OS	2	1
2/OD	1	1
2/OS	1	1
3/OD	1	1
3/OS	1	1
4/OD	1	1
4/OS	1	1
5/OD	2	1
5/OS	2	1
6/OD	1	1
6/OS	1	1
7/OD	1	1
7/OS	1	1
8/OD	0	0
8/OD	0	0
9/OD	1	1
9/OS	1	1
10/OD	1	1
10/OS	1	1
11/OD	1	1
11/OS	1	1
12/OD	1	1
12/OS	1	1
13/OD	1	1
13/OS	1	1

TABLE 40

Tear Film Debris/Aircraft Environment

Subject/Eye	Grade Baseline	120 min.
1/OD	1	1
1/OS	1	1
2/OD	1	1
2/OS	1	1
3/OD	1	1
3/OS	1	1
4/OD	1	1
4/OS	1	1
5/OD	1	1
5/OS	1	1
6/OD	1	1
6/OS	1	1
7/OD	1	1
7/OS	1	1
8/OD	1	1
8/OS	1	1
9/OD	0	1
9/OS	0	1
10/OD	1	1
10/OS	1	1
11/OD	1	1
11/OS	1	1

TABLE 41

Lens Debris/Normal Environment

Subject/Eye	Grade Baseline	120 min.
1/OD	0	1
1/OS	0	1
2/OD	0	1
2/OS	0	1
3/OD	0	0
3/OS	0	0
4/OD	0	0
4/OS	0	0
5/OD	0	0
5/OS	0	0
6/OD	0	0
6/OS	0	0
7/OD	0	0
7/OS	0	0
8/OD	0	1
8/OS	0	1
9/OD	0	0
9/OS	0	0
10/OD	0	1
10/OS	0	1
11/OD	1	1
11/OS	1	1
12/OD	0	1
12/OS	0	1
13/OD	1	1
13/OS	1	1

TABLE 42

Lens Debris/Simulated Aircraft Environment

Subject/Eye	Grade Baseline	120 min.
1/OD	0	0
1/OS	0	1
2/OD	0	1
2/OS	0	1
3/OD	0	1
3/OS	0	1
4/OD	0	1
4/OS	0	1
5/OD	0	0
5/OS	0	0
6/OD	0	0
6/OS	0	0
7/OD	0	0
7/OS	0	0
8/OD	0	1
8/OS	0	2
9/OD	0	1
9/OS	0	1
10/OD	0	1
10/OS	0	1
11/OD	0	0
11/OS	0	0

TABLE 43

Summary of the Statistics of the Two-Tailed Paired t-Tests for the Difference in Corneal Thickness Measurements

Test of MU = 0.00 vs MU N.E. 0.00

Normal environment, Baseline vs 120 mins.

N	Mean	STDEV	SE Mean	t	P Value
13	0.00304	0.01425	0.00395	0.77	0.46

Simulated Aircraft Environment, Baseline vs 120 mins.

N	Mean	STDEV	SE Mean	t	P Value
11	0.02059	0.01722	0.00519	3.97	0.0027

Normal vs Simulated Aircraft Environment

N	Mean	STDEV	SE Mean	t	P Value
11	0.01958	0.02436	0.00734	2.67	0.024

TABLE 44

Mean Corneal Thickness Values at Baseline and 120 Minutes for the Simulated Aircraft Environment

	N	Mean	STDEV	Min	Max
Baseline	N	Mean	STDEV	Min	Max
	11	0.51150	0.03870	0.42480	0.56020
120 Mins.	N	Mean	STDEV	Min	Max
	11	0.53200	0.03610	0.44990	0.57350

TABLE 45

Summary of the Statistics of the Two-Tailed Paired t-Tests for the Difference in LogMAR Visual Acuity

Test of MU = 0.00 vs MU N.E. 0.00

Normal Environment, High Contrast, Baseline vs 120 mins.

N	Mean	STDEV	SE Mean	t	P Value
13	-0.0123	0.0839	0.0233	-0.53	0.61

Normal Environment, Low Contrast, Baseline vs 120 mins.

N	Mean	STDEV	SE Mean	t	P Value
13	-0.0185	0.0557	0.0154	-0.20	0.25

Sim. Aircraft Env., High Contrast, Baseline vs 120 mins.

N	Mean	STDEV	SE Mean	t	P Value
11	-0.0255	0.0620	0.0187	1.36	0.20

Sim. Aircraft Env., Low Contrast, Baseline vs 120 mins.

N	Mean	STDEV	SE Mean	t	P Value
11	0.0036	0.0731	0.0220	0.16	0.87

TABLE 46

Summary Statistics for Baseline Corneal Thickness Measurements

Baseline - Normal Environment

N	Mean	Median	TRMean	STDEV	SEMean
26	0.51750	0.51835	0.51855	0.03341	0.00655

Min	Max	Q1	Q3
0.43930	0.57060	0.49128	0.54338

Baseline - Simulated Aircraft Environment

N	Mean	Median	TRMean	STDEV	SEMean
22	0.51362	0.52625	0.51576	0.03801	0.00810

Min	Max	Q1	Q3
0.42070	0.56380	0.49032	0.53580

APPENDIX D

FIGURES

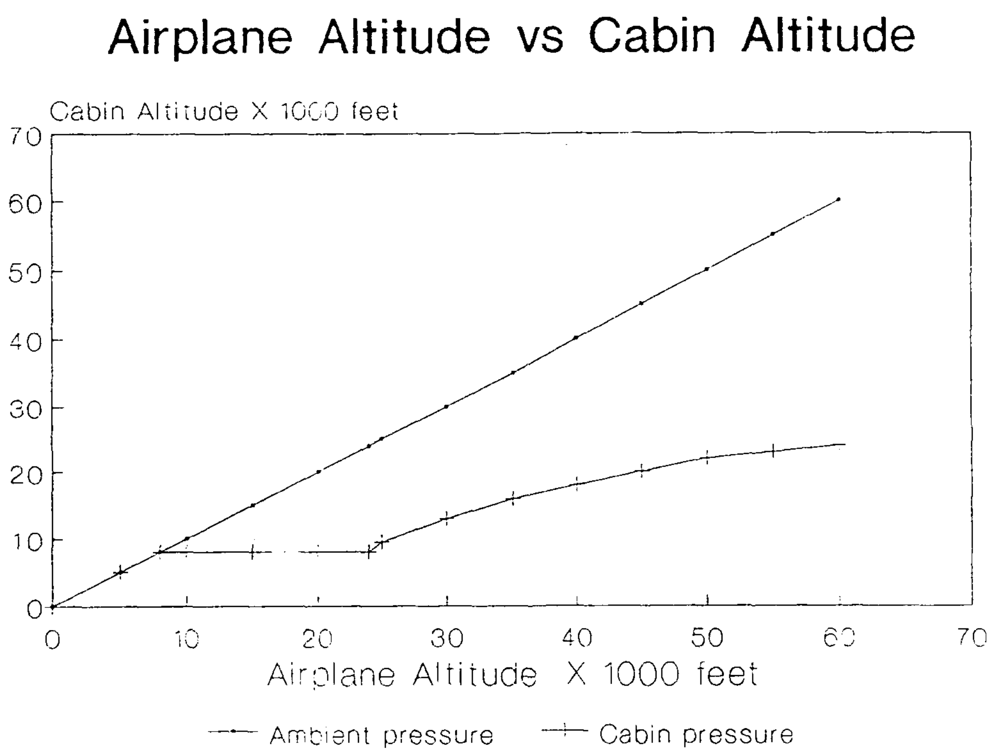


FIGURE 1

Aircraft Altitude vs Pressurized Cabin Altitude

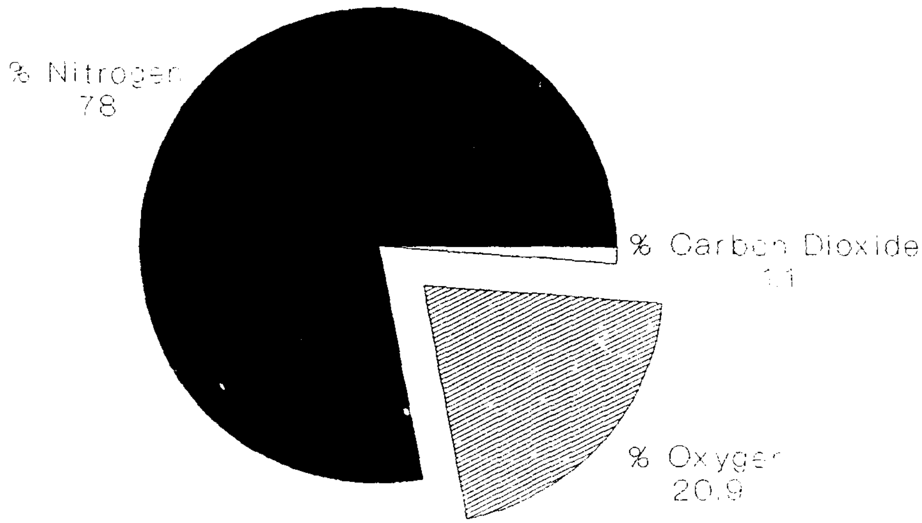


FIGURE 2

Percentage of Gases in the Atmosphere

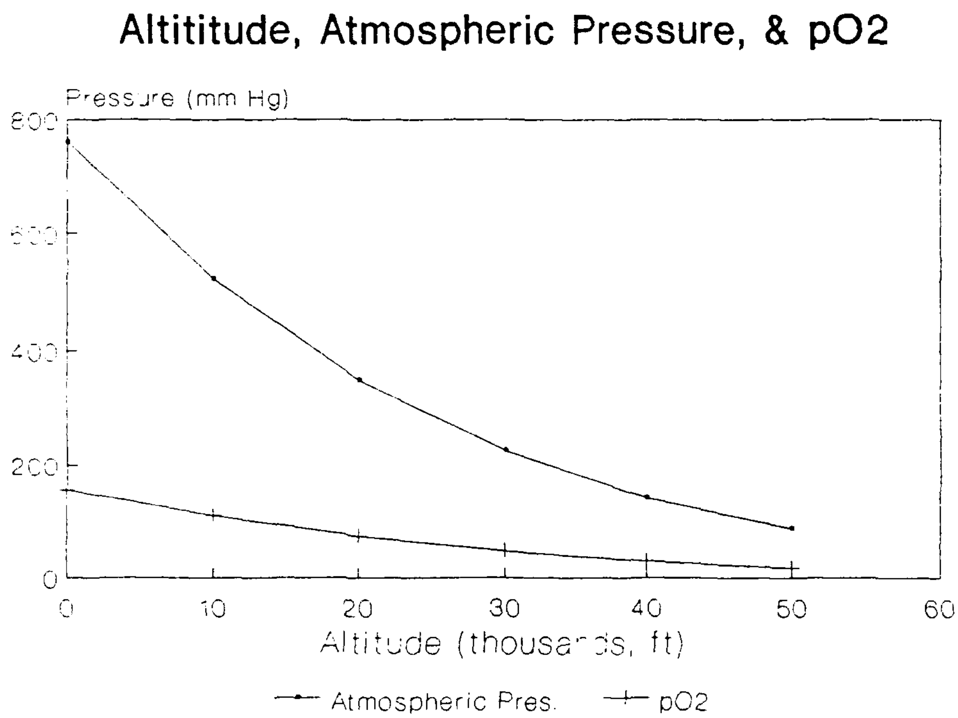


FIGURE 3

The Relationship Between Altitude, Atmospheric Pressure, and Partial Pressure of Oxygen

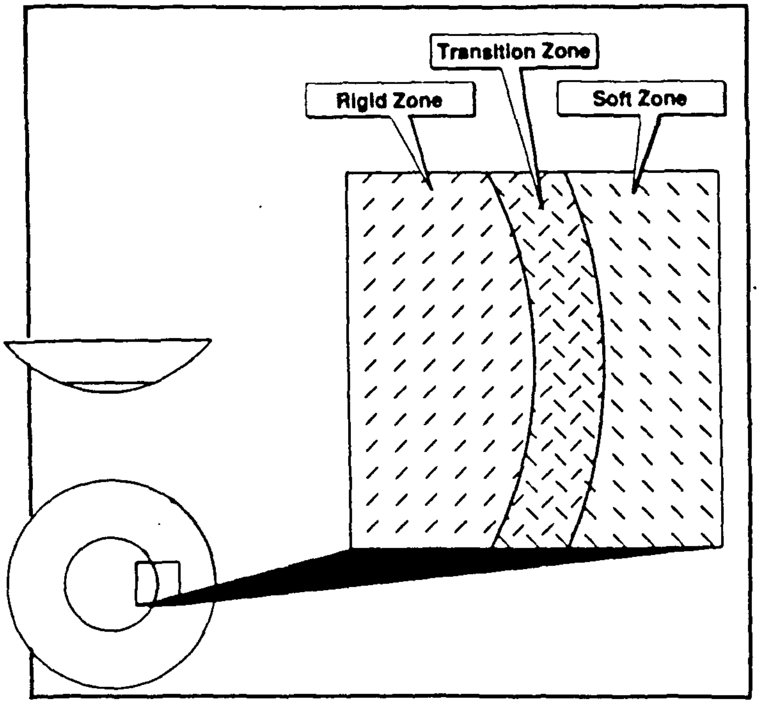


FIGURE 4

The Two-Phase Design of the Softperm Contact Lens(210)

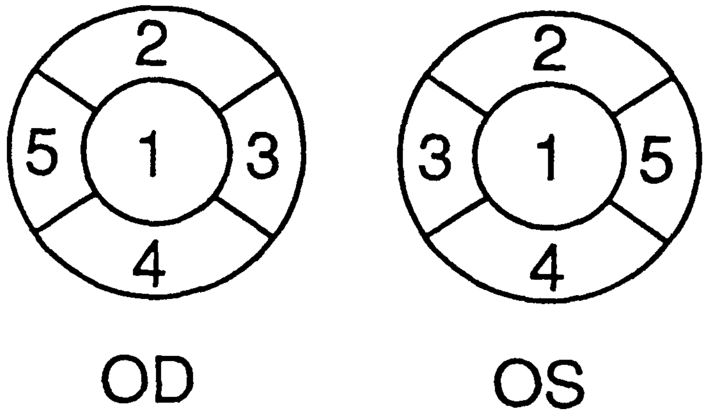


FIGURE 5

The Division of the Right and Left Corneas into Numbered Areas for the Recording of Staining Location(227)

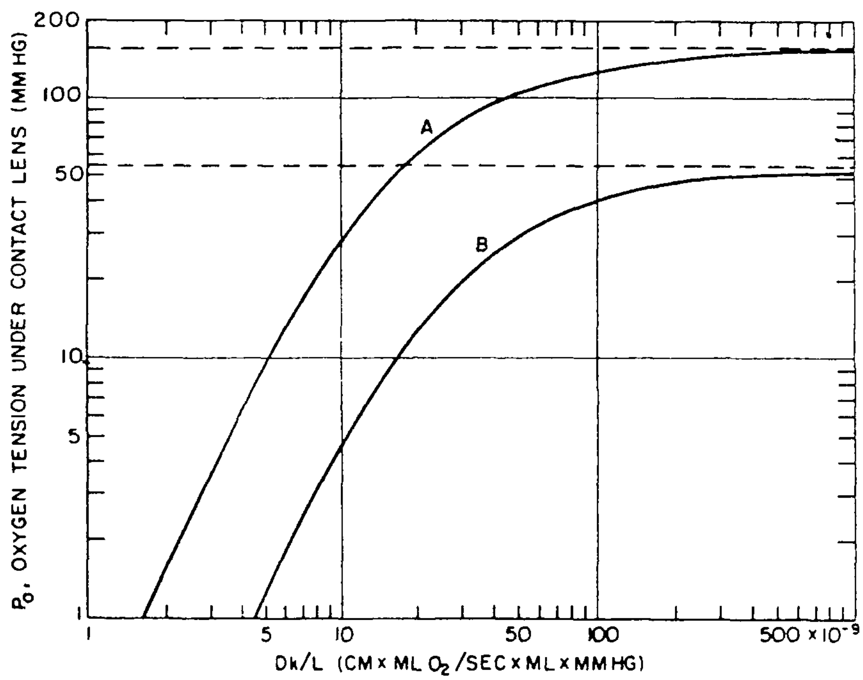


FIGURE 6

Oxygen Tension under a Contact Lens as a Function of Lens Dk/L for Open and Closed Eye(132)

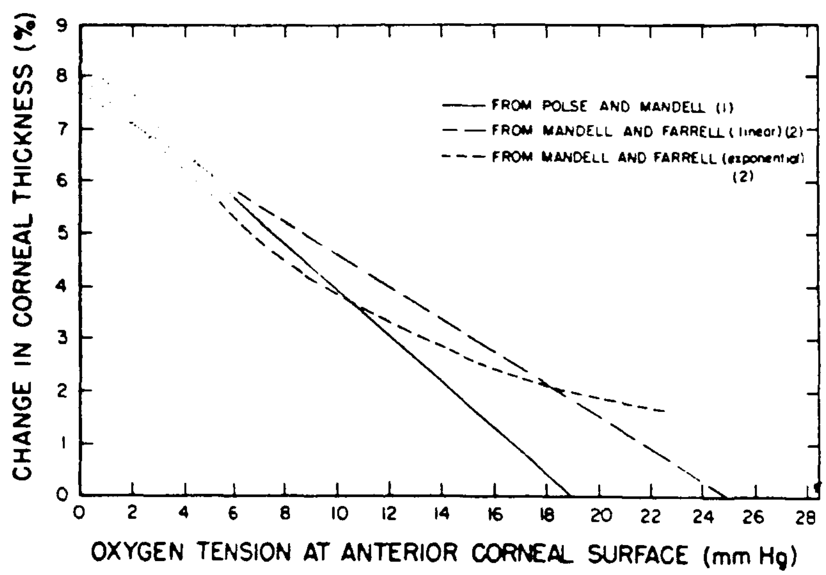


FIGURE 7

Mean Change in Central Corneal Thickness as a Function of Oxygen Tension at the Anterior Corneal Surface(99)

APPENDIX E

PLATES

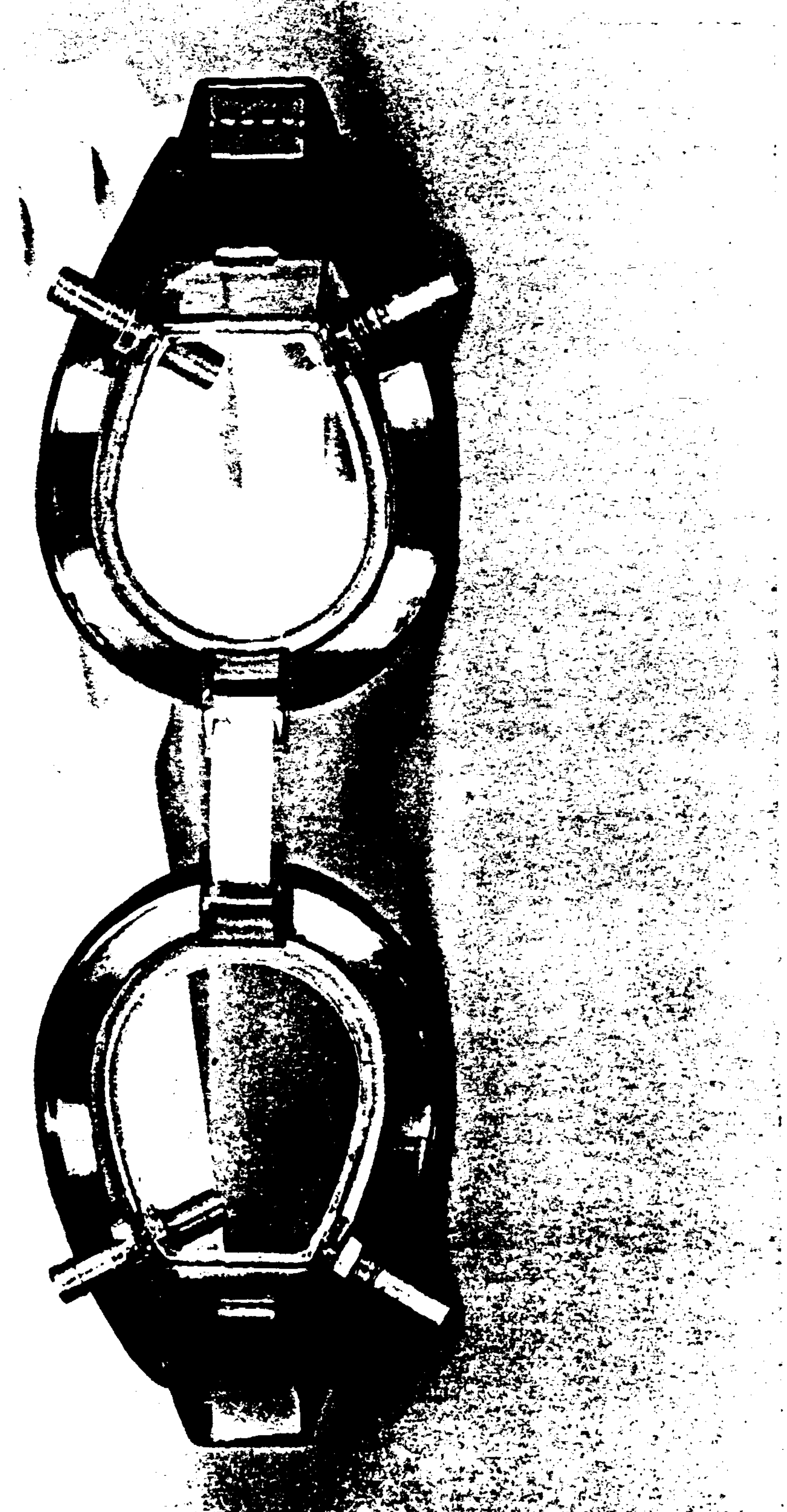


PLATE I

PLATE II

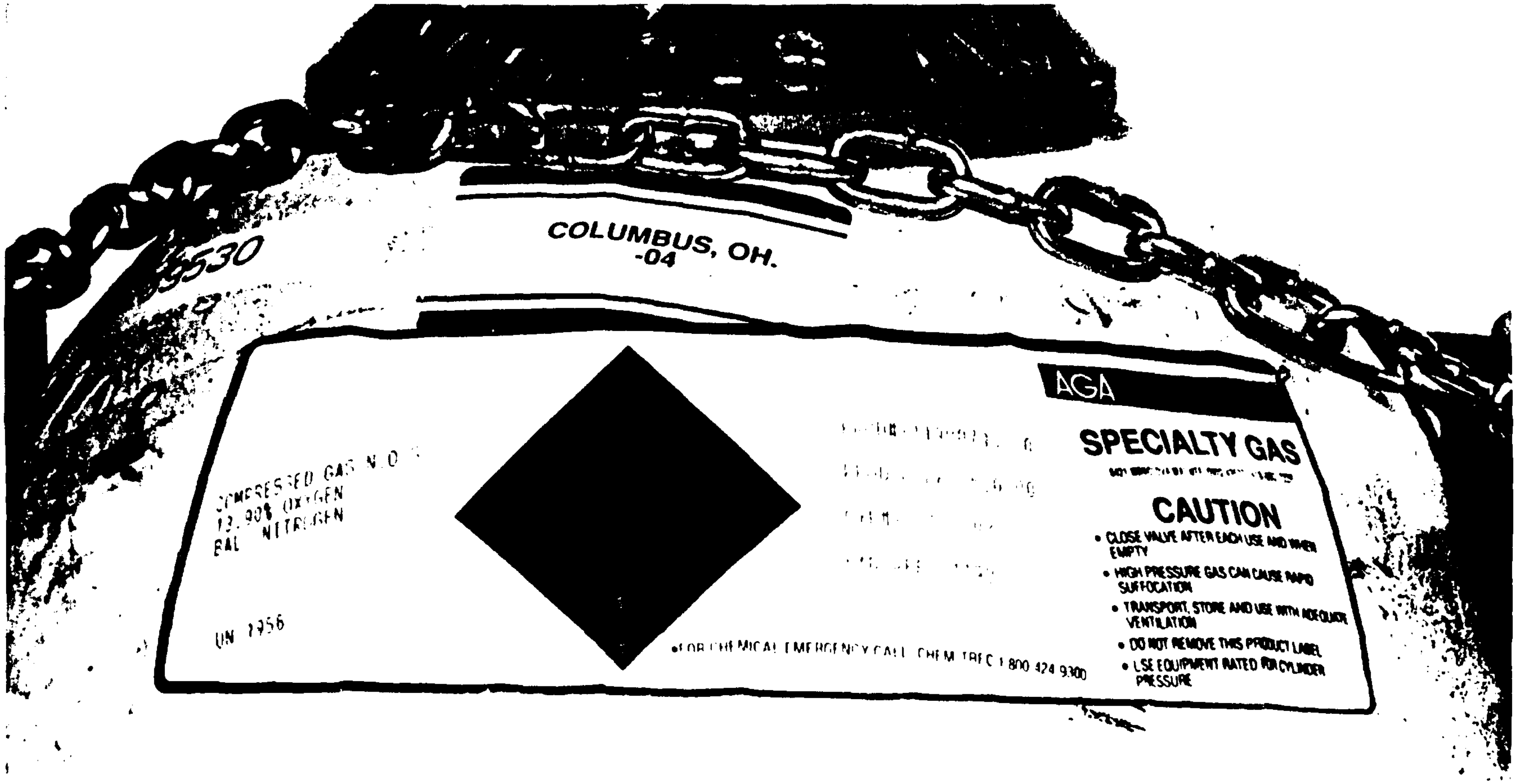

COLUMBUS, OH.
-04
AGA
SPECIALTY GAS
CAUTION
• CLOSE VALVE AFTER EACH USE AND WHEN EMPTY
• HIGH PRESSURE GAS CAN CAUSE RAPID SUFFOCATION
• TRANSPORT, STORE AND USE WITH ADEQUATE VENTILATION
• DO NOT REMOVE THIS PRODUCT LABEL
• USE EQUIPMENT RATED FOR CYLINDER PRESSURE
•FOR CHEMICAL EMERGENCY CALL CHEM TREC 1 800 424 9300

PLATE III

PLATE IV

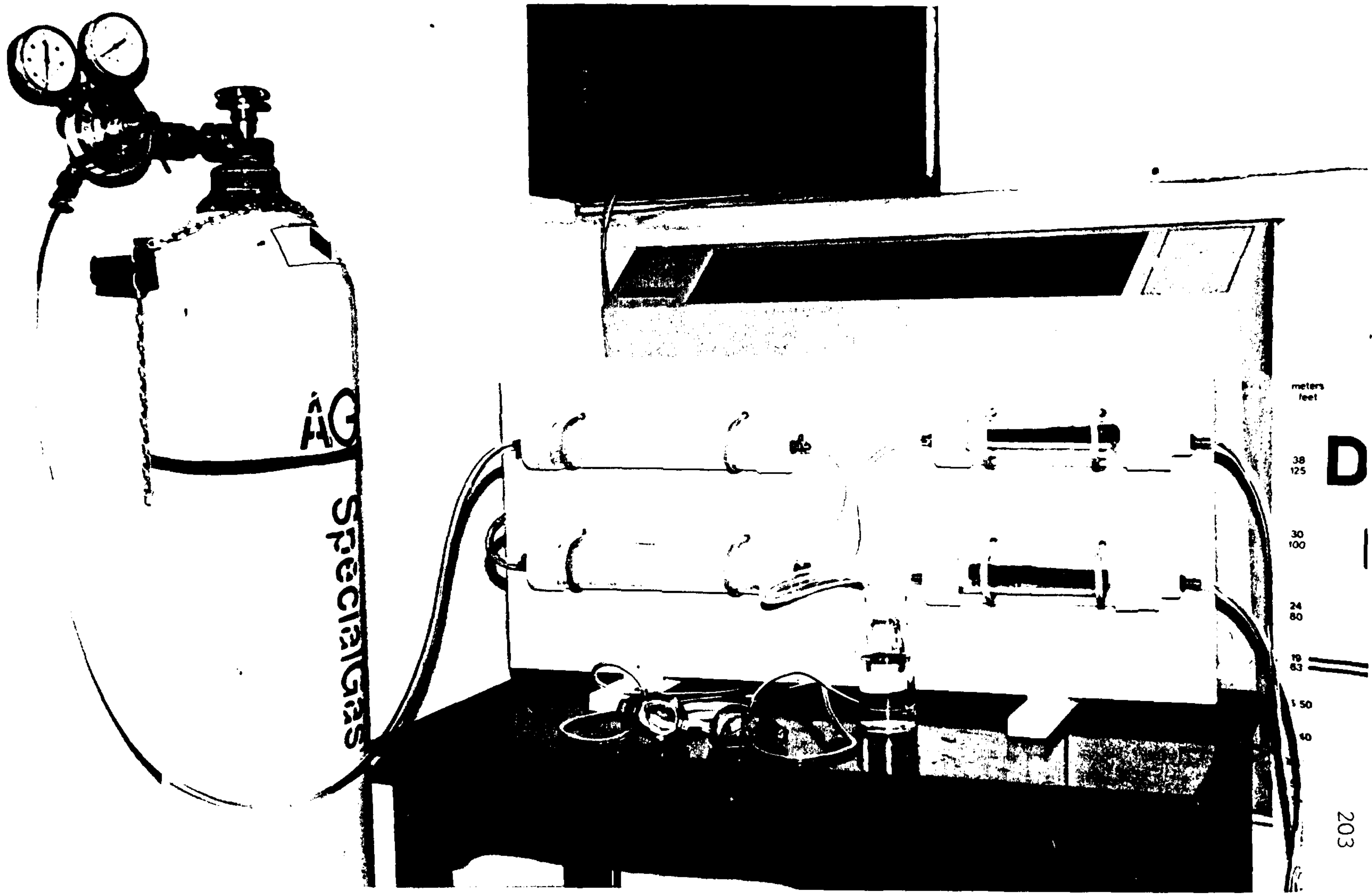


PLATE V

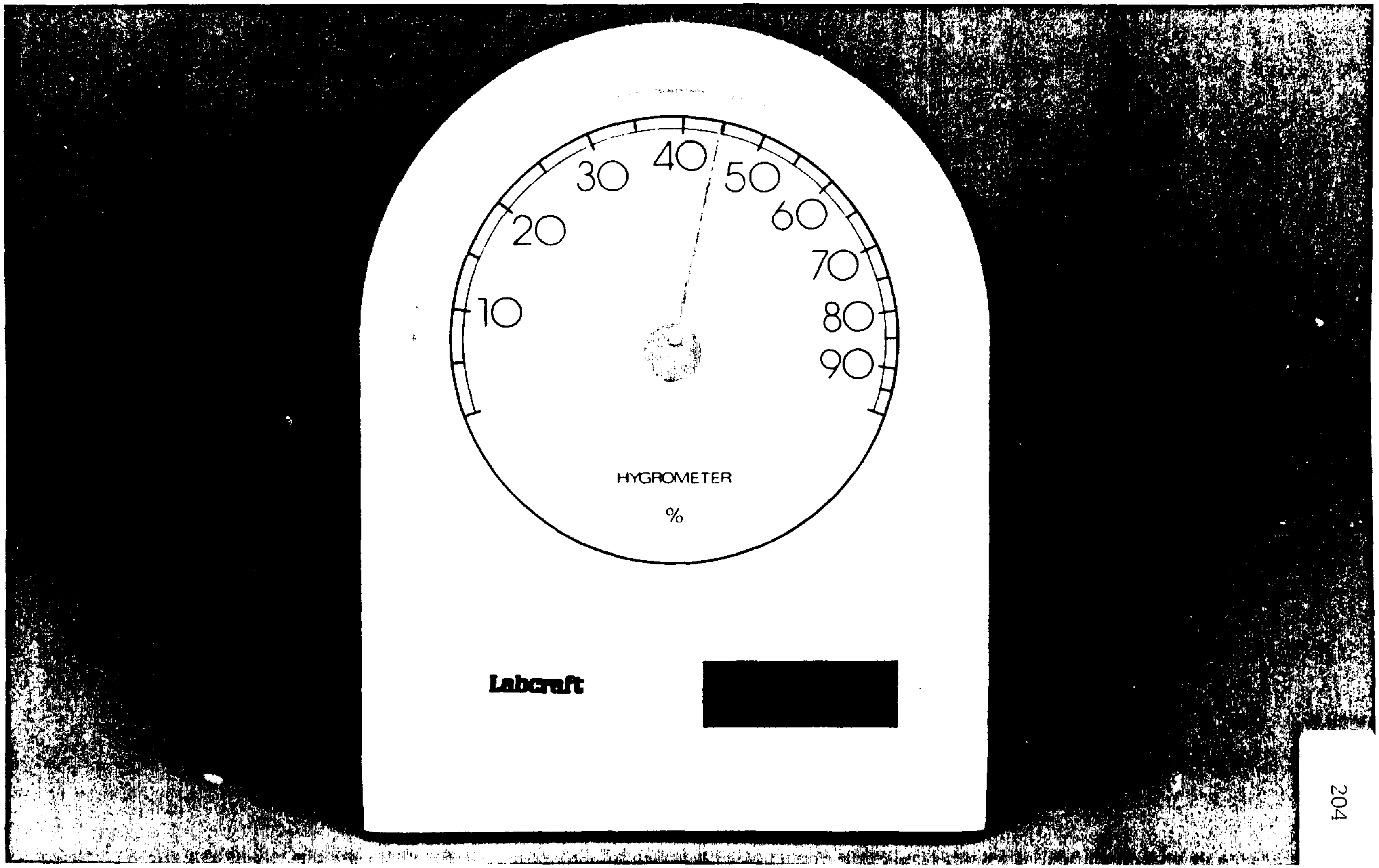


PLATE VI

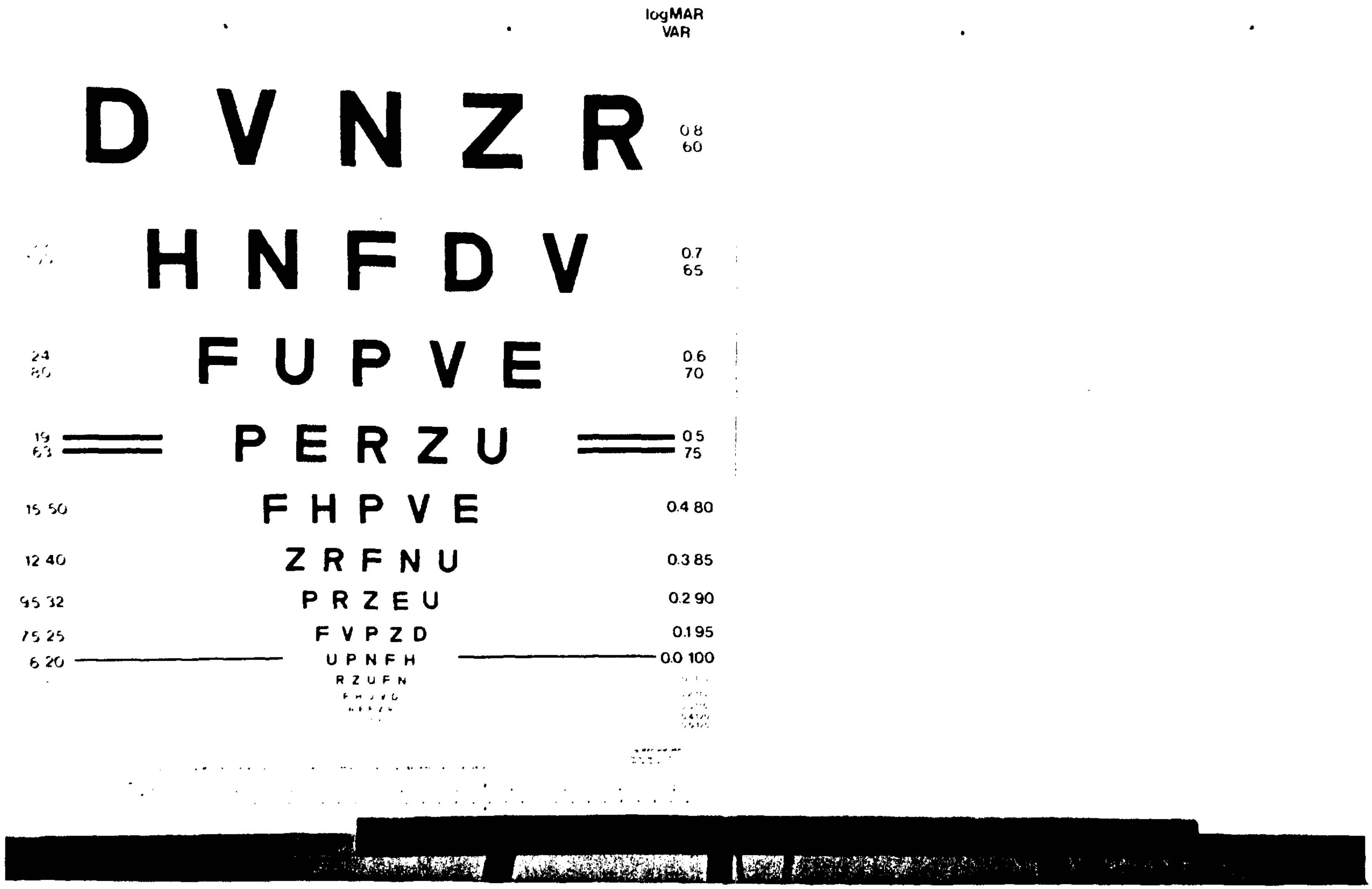

logMAR
VAR
D V N Z R
0.8
60
H N F D V
0.7
65
24
80
F U P V E
0.6
70
19
63
P E R Z U
0.5
75
15 50
F H P V E
0.4 80
12 40
Z R F N U
0.3 85
95 32
P R Z E U
0.2 90
75 25
F V P Z D
0.1 95
6 20
U P N F H
0.0 100
R Z U F N

PLATE VII

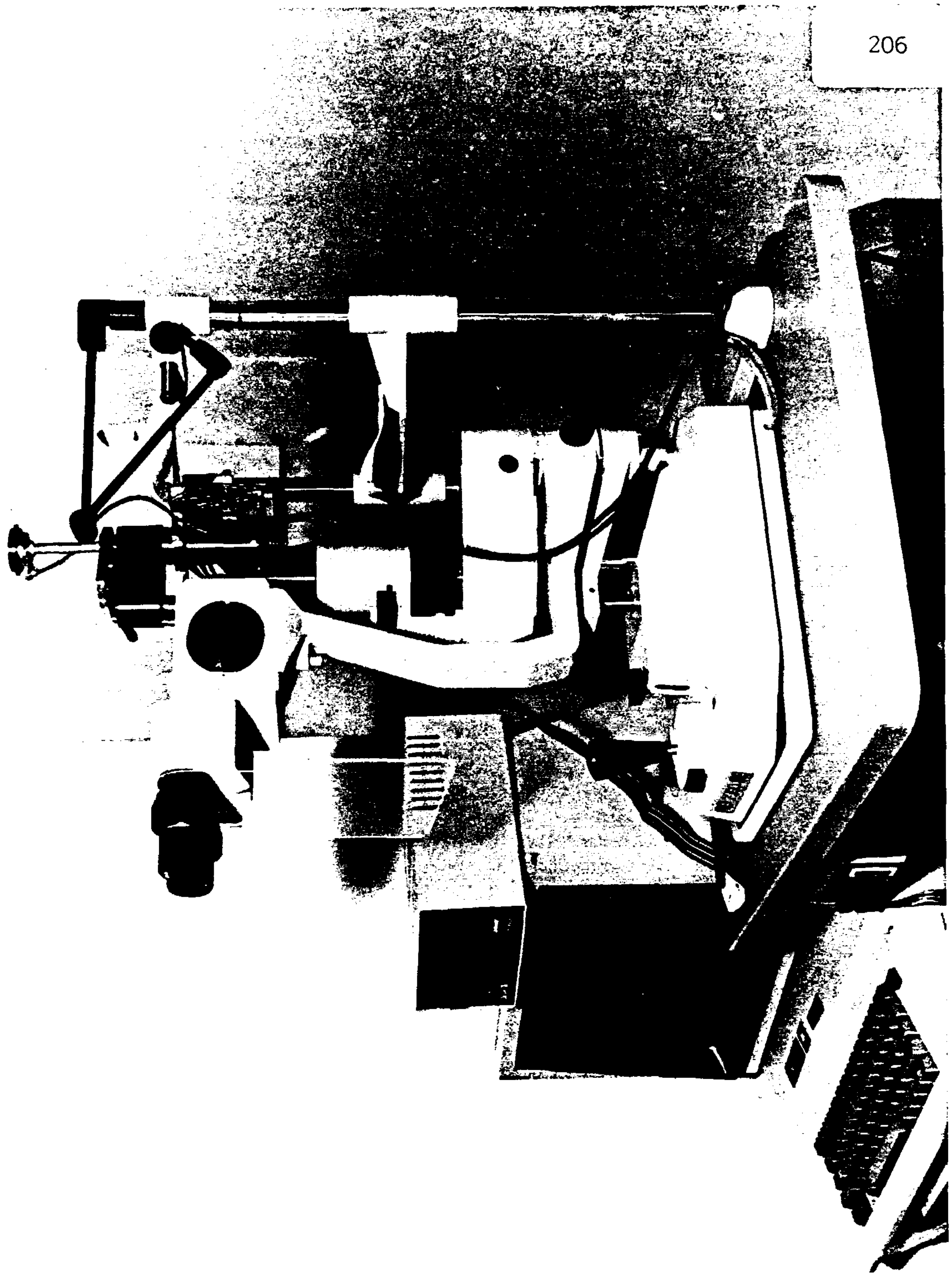
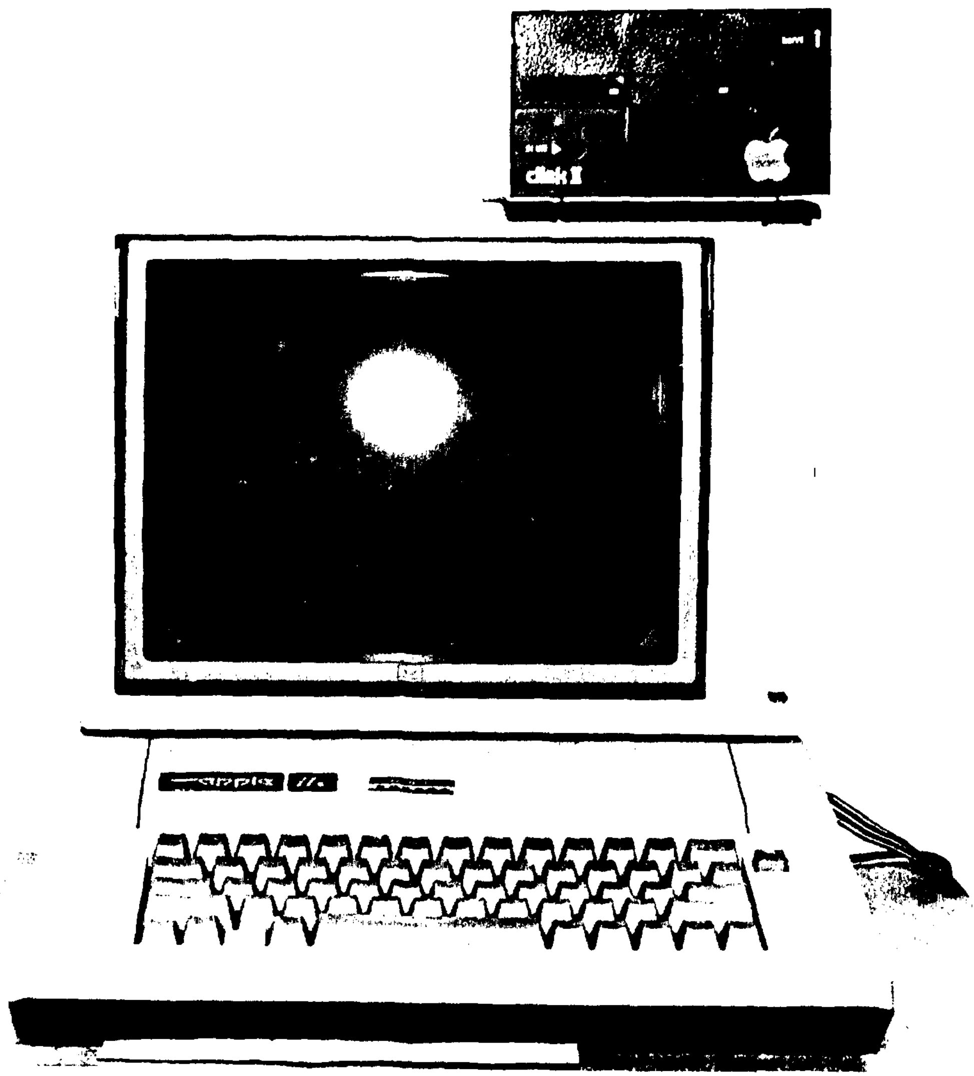


PLATE VIII



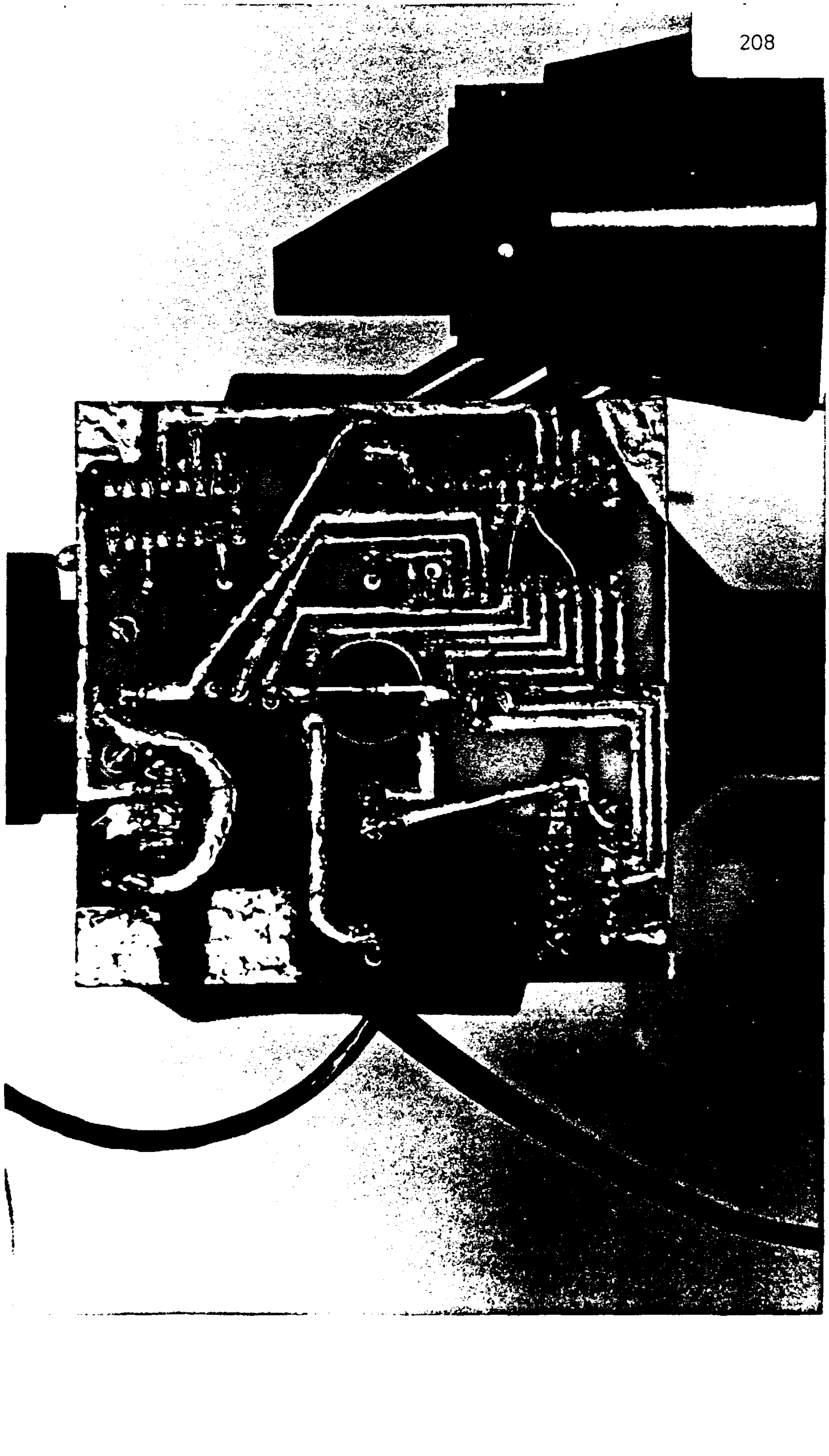


PLATE IX

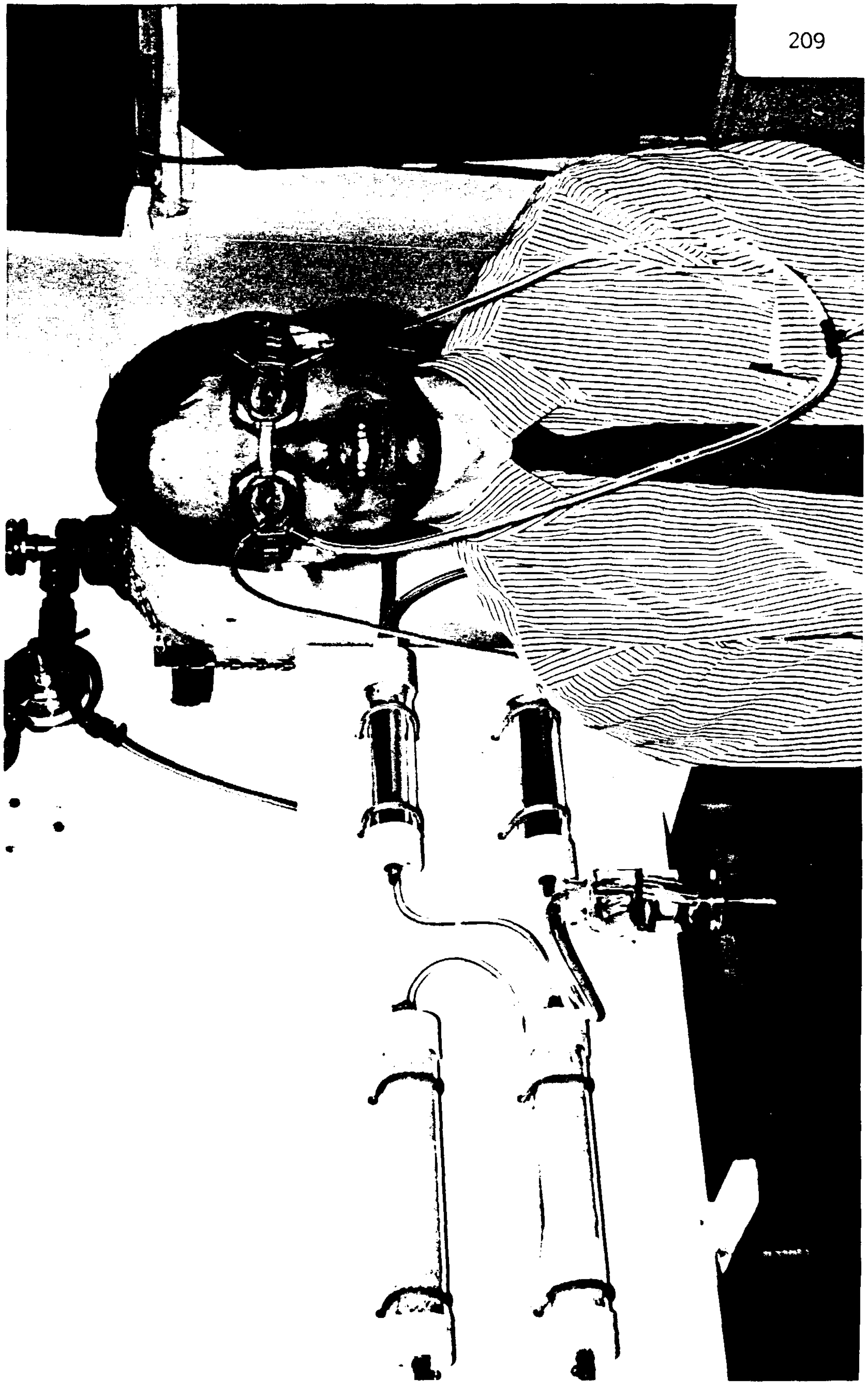


PLATE X

APPENDIX F

PACHOMETRY CALIBRATION

Calibration Table X-vs-Y

Y = 7.9829315E-03 X + -.548471359

Standard Error of A = .0809905098

Standard Error of B = 5.82868266E-04

Covariance S,Y = 1.79182699

Correlation Coeff = .992098035

Standard Error of Estimate of Y on X = .0174649458

Coefficient of Determination = .984258502

Lens Thickness (measured mm.)	Pachometry reading (electrical encoder)
0.419	123.08
0.519	134.18
0.619	147.46
0.729	159.42
0.492	127.38

X Mean = 138.304

Y Mean = .5556

Standard Deviation of X = 13.4002171

Standard Deviation of Y = .107825044

APPENDIX G

QUESTIONNAIRES

NAME________________________________ DATE_____________

QUESTIONNAIRE # 1

Softperm Contact Lens; Normal Environment.

Lens Comfort: (after adjusting to the lenses.)

Scale:

0 - No sensation or lens awareness/excellent comfort
1 - Occasional slight awareness
2 - Consistent awareness/slight discomfort
3 - Consistent discomfort
4 - Pain/very poor comfort

How would you rate the initial comfort of this lens?

0 1 2 3 4

How would you rate the comfort of this lens after wearing it for two hours.

0 1 2 3 4

How would you rate the comfort of this lens at the end of your normal wearing time.

0 1 2 3 4

Subjective Visual Acuity:

Do you have any comments concerning your visual acuity with these lenses.
(Is your vision satisfactory, stable, variable, etc.)

Wearing Time:

How many hours per day were you able to comfortably wear the Softperm lenses? ________.

Did you damage or lose any lenses during the study?

yes_____ no_____

NAME______________________________ DATE_____________

Questionnaire # 2

Softperm Contact Lens; Simulated Aircraft Environment

Lens Comfort:

Scale:

0 - No sensation or lens awareness/excellent comfort
1 - Occasional slight awareness
2 - Consistent awareness/slight discomfort
3 - Consistent discomfort
4 - pain/very poor comfort

Before exposure to dry air:

0 1 2 3 4

30 minutes:

0 1 2 3 4

60 minutes:

0 1 2 3 4

90 minutes:

0 1 2 3 4

120 minutes:

0 1 2 3 4

Please summarize any comfort changes you may have noticed during the past two hours.

Did you notice any changes in your vision during the past two hours? yes____ no____. If yes, please describe.

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